REMARKS

The applicants have studied the Final Office Action dated October 20, 2004, and respectfully request entry of this amendment under the provisions of 37 C.F.R. § 1.116 in that the amendments above and remarks below place the application and the claims in condition for allowance and in better form for consideration on appeal. By virtue of this amendment, claim 1 has been canceled without prejudice or disclaimer, and claims 2, 4, 9, 12, 16, 32, and 34-37 are requested to be amended; thus, claims 2-6, 9-16, and 32-40 are pending. Consideration and allowance of all the pending claims in view of the above amendments and the following remarks are respectfully requested.

The applicants note with appreciation that claims 5-6, 10-11, 15, and 33 have been allowed.

Claims 1-4, 7-9, 12-14, 16, 32, and 34-40 were rejected under 35 U.S.C. § 102(b) as being anticipated by Franetzki et al. With respect to claims 1 and 7-8, these claims have been canceled without prejudice or disclaimer; thus, this rejection is moot. With respect to claims 2-4, 9, 12-14, 16, 32, and 34-40, to advance prosecution of this application, claims 2, 4, 9, 12, 16, 32, and 34-37 have been amended to depend from allowed independent claim 5. Therefore, it is respectfully submitted that claims 2-4, 9, 12-14, 16, 32, and 34-40 are now in condition for allowance. Accordingly, withdrawal of the rejections of these claims under 35 U.S.C. § 103(a) is requested.

Additionally, the applicants respectfully request that the Examiner consider the Second Supplemental Transmittal of Information Disclosure Statement (IDS) and accompanying Form PTO-1449, which was filed on October 7, 2004. In reviewing the Final Office Action, the applicants noted that the Form PTO-1449 accompanying the Second Supplemental IDS was not attached to the Office Action. However, the applicants respectfully point out that the Second Supplemental IDS was filed on October 7, prior to the October 20, 2004 mailing date of the Final Office Action. Enclosed is a copy of the Second Supplemental IDS and accompanying Form PTO-1449 for the Examiner's reference. Further, enclosed is a copy of the return postcard,

indicating that the Patent Office received the Second Supplemental IDS and accompanying Form PTO-1449 on October 12, 2004, also prior to the October 20, 2004 mailing date of the Final Office Action. Accordingly, the applicants respectfully request that the Examiner consider the Second Supplemental IDS and accompanying Form PTO-1449.

The applicants respectfully submit that the foregoing amendments and remarks place the application and the claims in condition for allowance, and in better form for consideration on appeal. Entry of the foregoing amendments, and reexamination and reconsideration of the application as amended, are respectfully requested.

If, for any reason, the Examiner finds that the application is other than in condition for allowance and believes that a telephone interview would advance the prosecution of the application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

Date: January 19, 2005

By: _____
Vivian S. Shin
Reg. No. 43,919

MEDTRONIC MINIMED, INC.
18000 Devonshire Street
Northridge, CA 91325
Telephone: (818) 576-5291
Facsimile: (818) 576-6202

COPY

Serial No. 09/813,660 File No. PD-0448 CON Date Mailed 10/7/04 By: C. Pineiro
Title Control Tabs for Infusion Devices & Methods of Using....
Applicant Name: Medtronic MiniMed
The Following was received in the Patent & Trademark Office on the date stamped hereon:

____ Amendment
____ Preliminary Amendment
____ PCT Application Including
____ Pages Spec. ___Page Abstract___ Claims
____ Application for Patent Including
____ Pages Spec. ___Page Abstract___ Claims
____ Declaration (___Page(s))
____ Assignment with Recordation Form Cover
____ Power of Attorney by Assignee
____ General Power of Attorney
____ Letter of Transmittal
____ Amendment Transmittal
____ Transmittal of Missing Declaration
____ Notice of Non-Compliant Amendment
____ Notice to File Missing Parts
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Drawings: # of Sheets____ ____Formal ____Informal
____Transmittal of Formal Drawings
____Issue Fee Transmittal ____Form Part B
____Advance soft copy order
____Petition for Withdrawal from Issue
XX IDS Transmittal (XX Supplemental) - 2ND
XX IDS: 4 References XX Form PTO-1449
____Terminal Disclaimer
____Notice of Appeal
____Request for RCE
____Petition for an Extension of Time
____Certificate of Correction
____Request for Corrected Filing Receipt
____Corrected Filing Receipt
____PCT Request Form ____ Fee Calculation Sheet
____Certificate of Mailing
____Return postcard

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____ Assignment with Recordation Form Cover
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Drawings: # of Sheets____ ____Formal ____Informal
____Transmittal of Formal Drawings
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____Corrected Filing Receipt
____PCT Request Form ____ Fee Calculation Sheet
____Certificate of Mailing
____Return postcard

PATENT
PD-0448 CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	James D. Causey III et al.	
Serial No.:	09/813,660	Group Art Unit: 3763
Filed:	March 21, 2001	Examiner: Michael M. Thompson
Title:	CONTROL TABS FOR INFUSION DEVICES AND METHODS OF USING THE SAME	

SECOND SUPPLEMENTAL TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. ☐ The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office Action on the merits, whichever event occurs last. 37 C.F.R. §1.97(b) or

2. ■ The information disclosure statement transmitted herewith is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in §1.491 in an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last but *before* the mailing date of either:

   (1) a final action under §1.113 or

   (2) a notice of allowance under §1.311

   (3) or an action that otherwise closes prosecution.

CERTIFICATION OR FEE

A. Included with this transmittal is

   i. ■ a certification (set forth below) in accordance with 37 C.F.R. §1.97(e). (If for any reason the certificate set forth below should be

unsatisfactory, the Commissioner is provisionally authorized to charge the $180 fee (37 C.F.R. §1.17(p)) to Deposit Account No. 50-0621. A copy of this sheet is enclosed.)

OR

ii. ☐ the fee set forth in 37 C.F.R. §1.17(p) for submission of an information disclosure statement under §1.97(c) ($180.00).

3. ☐ The information disclosure statement transmitted herewith is being filed *after* a final action under §1.113 or a notice of allowance under §1.311, or an action that otherwise closes prosecution, whichever occurs first, but before, or simultaneously with the payment of the issue fee.

CERTIFICATION, PETITION AND FEE

A. In accordance with the requirements of 37 C.F.R. §1.97(d):

i. Set forth below is a certification as specified in 37 C.F.R. §1.97(e).

ii. Applicant hereby petitions for the consideration of the accompanying information disclosure statement. 37 C.F.R. §1.97(d)(ii).

iii. Applicant submits the petition fee set forth in §1.17(i)(1). ($180.00).

CERTIFICATION

(Required if 2Ai or 3 above is marked)

4. I, the person signing below, certify

■ that each item of information contained in the information disclosure statement was first cited in the attached communication from a foreign patent office in a counterpart foreign application and was not made in any communication dated more than three months prior to the filing of the statement. 37 C.F.R. §1.97(e)(1).

OR

☐ that no item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application or to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the statement. 37 C.F.R. §1.97(e)(2).

5. ■ If it should be determined that for any reason either an insufficient fee or an excessive has been paid, please charge any insufficiency or credit any overpayment necessary to ensure consideration of the information disclosure statement for the above-identified application to Deposit Account No. 50-0621. A copy of this petition is enclosed.

Respectfully submitted,

Date: October 7, 2004

By: Vivian S. Shin
Registration No. 43,919

MEDTRONIC MINIMED, INC.
18000 Devonshire Street
Northridge, CA 91325-1219
(818) 576-5291

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

on: October 7, 2004
Date of Deposit

Signature:
Vivian S. Shin, Reg. No. 43,919

FORM PTO-1449 IREV. 7.801	U.S. Department of Commerce PATENT AND TRADEMARK OFFICE	Attorney Docket No. PD-0448 CON	Serial No. 09/813,660
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant James D. Causey III et al.	
		Filing Date March 21, 2001	Group 3763

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Sub-Class	Filing Date If Appropriate
	AA						
	AB						
	AC						
	AD						
	AE						

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Sub-Class	Translation	
							Yes	No
	AF	6 6 5 9 5 5	06/30/88	CH	A61M	5/00	X	
	AG	0 4 9 7 0 4 1	08/05/92	EPO	A61M	5/172		X
	AH	9 4 0 7 1 8 6	03/31/94	PCT	G05B	19/12		X

OTHER DOCUMENTS

	AI	Japanese Patent Office Decision of Final Rejection for Patent Application Serial No. 2001-501284, Mailing Date 08/10/04 (translation included)
	AJ	

Examiner	Date Considered

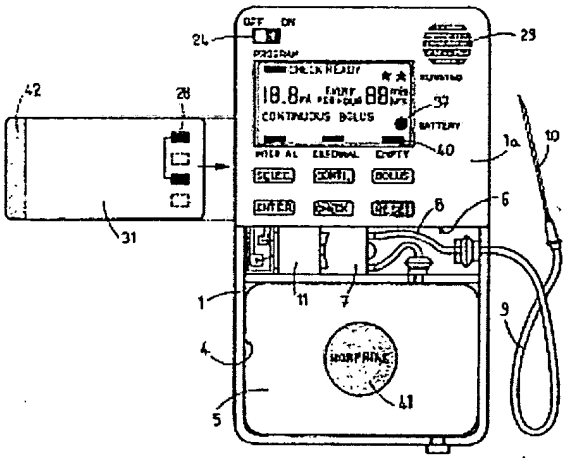
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Manually programmable injector - has interchangeable drug cartridge, and data input setting the valves which can be manually selected

Patent number:	CH665955
Publication date:	1988-06-30
Inventor:	RAY CLAUDE
Applicant:	UNIVERSO SA
Classification:	
- international:	A61M5/00
- european:	A61M5/172
Application number:	CH19850004925 19851119
Priority number(s):	CH19850004925 19851119

Abstract of **CH665955**

A drug injector has an interchangeable cartridge holding the drug, a pump, an electronic circuit controlling the frequency and duration of the pumps operation, a manual programmer for the circuit, and a data input setting the frequency and duration values which can be manually selected.
The data input pref. receives a card which unlocks a cover closing the cartridge when inserted.
ADVANTAGE - Dangerous doses cannot be administered.



CH 665 955 A5

(19) CONFÉDÉRATION SUISSE
OFFICE FÉDÉRAL DE LA PROPRIÉTÉ INTELLECTUELLE

(11) CH 665 955 A5

(51) Int. Cl.⁴: A 61 M 5/00

Brevet d'invention délivré pour la Suisse et le Liechtenstein
Traité sur les brevets, du 22 décembre 1978, entre la Suisse et le Liechtenstein

(12) FASCICULE DU BREVET A5

(21) Numéro de la demande: 4925/85

(22) Date de dépôt: 19.11.1985

(24) Brevet délivré le: 30.06.1988

(45) Fascicule du brevet publié le: 30.06.1988

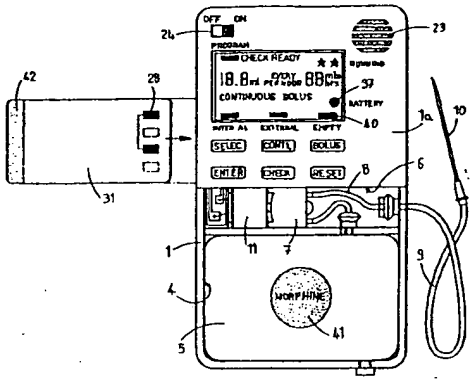
(73) Titulaire(s):
Universo S.A., La Chaux-de-Fonds

(72) Inventeur(s):
Ray, Claude, La Chaux-de-Fonds

(74) Mandataire:
Jean S. Robert, Landecy-Genève

(54) Appareil à injecter un produit pharmaceutique.

(57) L'appareil comprend un compartiment (4) destiné à contenir une cartouche (5) de produit à injecter. Le programme des doses et régimes d'injection est introduit dans l'appareil à l'aide de touches. Afin d'éviter des erreurs de dosage, l'entrée des données ne peut être effectuée que si une carte (31) portant un circuit imprimé (28) est engagée dans l'appareil. De telles cartes permettent de sélectionner des plages possibles d'introduction de données et sont établies en fonction du produit à administrer. Dans la pratique, trois cartes suffisent, correspondant à trois catégories différentes de produits. La cartouche (5) présente une zone colorée (41) de même que la carte (31), ce qui permet de juger d'un coup d'oeil si aucune erreur n'a été commise. La carte (31) doit en outre être engagée dans le boîtier (1) de l'appareil pour que le compartiment (4) de la cartouche (5) de produit soit accessible.



REVENDICATIONS

1. Appareil à injecter un produit pharmaceutique comprenant un réservoir pour le produit à injecter se présentant sous la forme d'une cartouche interchangeable, une pompe d'injection et un circuit électronique commandant la durée et la fréquence des périodes de fonctionnement de la pompe et, par conséquent, des injections, caractérisé par le fait qu'il comprend deux moyens d'entrée d'informations destinées à piloter le circuit électronique, les premiers, opérables manuellement, agencés pour permettre à l'opérateur de déterminer la durée et la fréquence des périodes de fonctionnement de la pompe, et les seconds, actionnables au moyen d'un support d'informations préétablies, permettant de déterminer les plages de durées et de fréquences aptes à être sélectionnées par lesdits premiers moyens d'entrée d'informations.

2. Appareil suivant la revendication 1, dont le bâti présente un logement destiné à recevoir la cartouche de produit à injecter, logement se fermant à l'aide d'un couvercle, caractérisé par le fait que le support d'informations agissant sur lesdits seconds moyens d'entrée d'informations est constitué par une carte libérant, lorsqu'elle est en place sur l'appareil, des moyens de verrouillage dudit couvercle, de telle manière que le logement pour la cartouche ne soit accessible que lorsque des informations sont fournies auxdits seconds moyens d'entrée d'informations.

3. Appareil suivant la revendication 1, caractérisé par le fait que le support d'informations agissant sur lesdits seconds moyens d'entrée d'informations porte un signe d'identification du produit à injecter se retrouvant sur la cartouche contenant ce produit, de manière que l'opérateur sache d'un seul coup d'œil qu'il utilise bien le support correspondant au produit prêt à être injecté.

4. Appareil suivant la revendication 3, caractérisé par le fait qu'il est agencé de façon que, lorsqu'il est prêt à l'emploi, les signes distinctifs de la cartouche de produit à injecter et du support d'informations soient visibles simultanément, de façon à permettre un ultime contrôle de la correspondance entre le support d'informations et le produit à injecter.

DESCRIPTION

La présente invention a pour objet un appareil à injecter un produit pharmaceutique comprenant un réservoir pour le produit à injecter se présentant sous la forme d'une cartouche interchangeable, une pompe d'injection et un circuit électronique commandant la durée et la fréquence des périodes de fonctionnement de la pompe et, par conséquent, des injections.

De tels appareils sont connus.

Ils présentent le danger qu'une erreur de manipulation, lors de l'introduction des données déterminant les quantités et durées d'injection du produit, conduise à administrer des doses de produit pharmaceutique qui peuvent non seulement être contre-indiquées mais aussi être dangereuses.

Le but de la présente invention est de remédier à cet inconvénient en fournissant un appareil qui rende hautement improbables, voire impossibles, de telles erreurs de manipulation et qui, en particulier, empêche qu'y soient introduites des informations de pilotage de la pompe d'injection qui seraient incompatibles avec le produit garnissant, au moment de la manipulation, l'appareil, ou qui rende impossible l'introduction, dans l'appareil, d'un produit pharmaceutique alors qu'il est programmé pour un mode d'administration donné.

Ces buts sont atteints grâce aux moyens définis dans la revendication 1.

Le dessin représente, à titre d'exemple, une forme d'exécution de l'objet de l'invention.

La fig. 1 est une vue en plan, son couvercle étant ôté, d'un appareil servant à injecter un produit pharmaceutique.

La fig. 2 est une coupe schématique d'un détail de cet appareil, à plus grande échelle.

La fig. 3 représente, très simplifié, le schéma de fonctionnement de cet appareil, et

les fig. 4 et 5 sont des diagrammes illustrant deux régimes de fonctionnement, en continu et par intermittence, de l'appareil.

L'appareil représenté comprend un boîtier parallélépipédique 1 dont une partie est recouverte par une plaque frontale fixe 1*a* et dont une partie est munie d'un couvercle mobile 2, non représenté à la fig. 1, articulé en 3 (fig. 2). Ce couvercle, lorsqu'il est soulevé, découvre, ménagé dans le boîtier 1, un compartiment 4 destiné à contenir une cartouche 5 enfermant le produit à injecter et un compartiment 6 destiné à contenir une pompe à membrane 7 d'injection du produit, le conduit de refoulement de cette pompe, désigné par 8, étant relié, par un conduit souple 9, à une aiguille hypodermique d'injection 10. La membrane de la pompe 7 est actionnée par un poussoir commandé lui-même par un solénoïde 11.

Il est à remarquer que la cartouche 5 et la pompe 7 se mettent en place et s'enlèvent simultanément, chaque cartouche étant livrée avec une pompe qui forme un tout avec elle, non destinée à en être séparée.

Le circuit électronique de l'appareil (fig. 3) comprend un microprocesseur 12, un tabulateur 13, à six touches d'entrée de données 14, 15, 16, 17, 18 et 19, ainsi qu'un dispositif d'affichage 20. L'appareil comprend en outre un dispositif de contrôle 21 de l'état de la pile, désignée par 22, un ronfleur 23, un interrupteur principal «OFF-ON» à commande manuelle 24, un interrupteur 25 qui se ferme lors de la mise en place de la pompe, laquelle présente à cet effet, sur la face postérieure de son boîtier, un plot de contact et un ensemble de lames élastiques de contact, représentées schématiquement à la fig. 3 comme un simple interrupteur 26, mais dont l'une est visible à la fig. 2, avec lesquelles coopère l'un ou l'autre de trois circuits imprimés 27, 28 et 29 portés par trois cartes-programme 30, 31 et 32, respectivement. De plus, à la fig. 3, la ligne 33 est la ligne assurant l'effaçage de l'affichage lorsque la pompe 7 est retirée de l'appareil, la ligne 34 est la ligne de fonctionnement, la ligne 35 est celle de la purge que l'on effectue avant la mise en service de l'appareil afin d'éliminer l'air que pourraient contenir le conduit 9 et l'aiguille 10, la ligne 36 est celle qui commande l'avertisseur sonore 23 ainsi qu'un témoin lumineux 37 lorsque la pile est déchargée et la ligne 38 est celle qui commande l'avertisseur sonore et un témoin lumineux 40 lorsque la cartouche 5 est vide.

Les trois cartes-programme 30, 31 et 32, dont le nombre pourrait être différent, correspondent à trois catégories de produits pharmaceutiques allant des plus anodins, qui peuvent être administrés sans danger jusqu'à raison de 50 ml/h, jusqu'aux plus actifs ou dangereux, qui ne peuvent être administrés sans danger que jusqu'à raison de 0,5 ml/h, par exemple la morphine, en passant par les médicaments dont la dose est limitée à 5 ml/h. Afin que ces doses ne soient pas dépassées, chaque carte-programme détermine une plage des durées et des fréquences de fonctionnement de la pompe 7 qui peuvent être introduites dans l'appareil à l'aide du tabulateur 13 lorsque la carte correspondante y est engagée. Toute donnée sortant des limites de la plage déterminée par la carte-programme engagée dans l'appareil ne peut pas être introduite dans celui-ci. De plus, le circuit est agencé de façon que, lorsque aucune carte ne se trouve dans l'appareil, aucune donnée ou information ne puisse être introduite dans celui-ci.

Afin d'éviter tout risque d'erreur de concordance entre la carte-programme utilisée et la cartouche de produit mise en place dans l'appareil, chaque cartouche 5 de produit présente une zone circulaire 41 colorée alors que les cartes-programme présentent une zone colorée 42. Il suffit que les couleurs de la carte-programme et de la cartouche introduites dans l'appareil soient les mêmes pour que toute erreur d'introduction de données ou informations soit impossible.

Il est à remarquer qu'un ultime contrôle, au moment de l'utilisation de l'appareil, est possible car, lorsque la carte-programme est en place dans celui-ci, sa zone colorée 42 dépasse hors du boîtier 1 et, par conséquent, est visible, alors que la zone colorée 41 de la cartouche est visible à travers une ouverture circulaire du couvercle 2.

A titre de sécurité, et afin que seuls les détenteurs de cartes-programme puissent effectuer des manipulations de l'appareil, le dispositif de fermeture du couvercle 2, représenté schématiquement à la fig. 2, est agencé de façon que l'ouverture de celui-ci ne puisse être effectuée qu'en utilisant à cet effet l'une ou l'autre des trois cartes-programme 30, 31 et 32 que l'on peut, par conséquent, appeler également «cartes-clés». Le couvercle présente une partie 2*a* en forme de crochet avec laquelle coopère un verrou 43 soumis à l'action d'un ressort à boudin 44 qui tend à le maintenir dans sa position de fermeture représentée en traits mixtes. L'engagement d'une carte produit l'ouverture de ce verrou, l'extrémité de la carte butant contre un doigt 43*a* que présente le verrou à cet effet. Une fois le couvercle 2 ouvert, et la carte relâchée, le ressort 44 ramène le verrou dans sa position de travail, ce qui repousse légèrement la carte à l'extérieur du boîtier 1, rendant visible sa zone colorée 42.

Le présent appareil s'utilisera de la façon suivante: la carte-clé correspondant au produit pharmaceutique que l'on désire administrer au patient est introduite dans le boîtier 1 puis poussée à fond, ce qui amène le couvercle 2 à s'ouvrir sous l'effet d'un ressort de rappel 45. La carte-clé est alors relâchée, ce qui l'amène, sous l'effet du ressort de rappel 42 du verrou, à occuper sa position de travail dans laquelle le circuit imprimé dont elle est munie entre en contact avec les lames élastiques de contact 26 (fig. 2). La cartouche 5 du produit précédemment administré et la pompe 7 qui lui est associée sont retirées, ce qui, automatiquement, produit l'effaçage du programme précédent et de l'affichage correspondant. Une nouvelle cartouche 5 avec sa pompe 7 est mise en place dans l'appareil, ce qui rétablit le contact et permet à une nouvelle programmation d'être effectuée, moyennant bien sûr que la carte-programme ou carte-clé soit laissée en place dans l'appareil.

L'opérateur vérifiera à ce moment que les couleurs de la carte et de la cartouche de produit soient les mêmes.

L'opérateur choisit alors, en appuyant sur la touche 15 ou la touche 16, respectivement, le mode d'administration du produit envisagé, soit l'injection en régime continu (touche 15) ou l'injection en régime intermittent ou bolus (touche 16). Le régime d'injection choisi apparaît alors dans la fenêtre d'affichage.

Dans le cas où le régime continu d'injection est choisi, l'une ou l'autre des possibilités de volumes d'injection que l'appareil a en mémoire peut être sélectionnée, en fonction de ce qu'autorise la carte-clé introduite dans l'appareil. A cet effet, l'opérateur appuie sur la touche 14 (SELEC), ce qui amène les volumes d'injection disponibles, définis par les contacts de la carte-clé, à défiler dans la fenêtre d'affichage, à raison d'une par pression sur la touche. Lorsque la valeur désirée apparaît, l'opérateur appuie sur la touche 17 (ENTER) de manière à la programmer.

Le régime continu est graphiquement représenté à la fig. 4 où les temps sont portés sur l'axe horizontal. Chaque barre verticale représente une impulsion de la pompe, débitant 10 µl du produit à administrer. Les intervalles de temps, constants, sont indiqués par la distance «Intervalle». La variation d'un volume d'injection à l'autre, parmi les neuf volumes différents en mémoire dans l'appareil, s'obtient par une variation desdits intervalles.

Si, au contraire, c'est le régime intermittent d'injection qui est adopté, un rythme unique, utilisant l'intervalle de temps le plus court du régime continu, soit 0,72 sec, est repris de ce dernier régime. Cinq possibilités de volumes d'injection correspondant à cinq durées d'injection sont en mémoire dans l'appareil et se combinent avec cinq périodes, elles aussi en mémoire. Les doses journalières dépendent des combinaisons du volume et de la période choisie. Les valeurs des volumes défilent dans la fenêtre d'affichage pour chaque pression sur la touche 14 (SELEC) et, lorsque la valeur désirée apparaît, l'opérateur presse la touche 17 (ENTER). Ce sont ensuite les périodes qui défilent lorsque la touche 14 est actionnée, la période choisie étant introduite dans l'appareil à l'aide de la touche 17.

Le régime intermittent est graphiquement représenté à la fig. 5 où les temps sont portés sur l'axe horizontal, comme pour le cas de la fig. 4. Dans ce mode de fonctionnement, des trains d'impulsions (de cinq chacun dans l'exemple représenté), produisant chacune un débit de 10 µl du produit à administrer, sont envoyés à la pompe à des périodes variables. L'intervalle entre les différentes impulsions de chaque train est, comme indiqué, de 0,72 sec.

Comme indiqué également, les variations dans les quantités du produit à administrer sont obtenues par les combinaisons du volume et de la période choisie, c'est-à-dire que l'on peut augmenter et diminuer le nombre des impulsions dans chaque train et la fréquence de l'envoi de ceux-ci.

Au moment de l'emploi de l'appareil, celui-ci est purgé de l'air qu'il pourrait contenir et la carte-programme ou carte-clé est retirée, ce qui déclenche la mise en service de l'appareil qui commence alors à fonctionner.

Il est à remarquer que, lorsque le réservoir du produit est prêt à être vide, l'avertisseur sonore 23 est automatiquement mis en marche, produisant un signal du type bip-bip, en même temps que s'allume la lampe-témoin 40 (EMPTY).

De même, lorsque la tension de la pile 22 diminue, l'avertisseur sonore 23 se met en marche et le témoin lumineux 37 (BATTERY) s'éclaire.

En variante, l'appareil pourra être plus sophistiqué que ce n'est le cas dans l'exemple représenté et permettre à l'opérateur non pas de choisir entre un certain nombre de volumes d'injections pour le régime continu et un certain nombre de combinaisons de volumes et de périodes pour le régime intermittent, mais de composer lui-même les valeurs qu'il entend utiliser.

A cet effet, l'appareil comprendra un tabulateur de dix touches numérotées de 0 à 9 permettant l'introduction des données.

En variante également, on pourra prévoir le cas où la carte-programme sera supprimée et où, en lieu et place, ce sera la cartouche elle-même du produit à administrer qui portera un circuit imprimé tel que les circuits 27, 28 et 29 des cartes de l'appareil décrit et représenté, sélectionnant la plage des données qu'il sera possible d'utiliser pour le produit pharmaceutique correspondant.

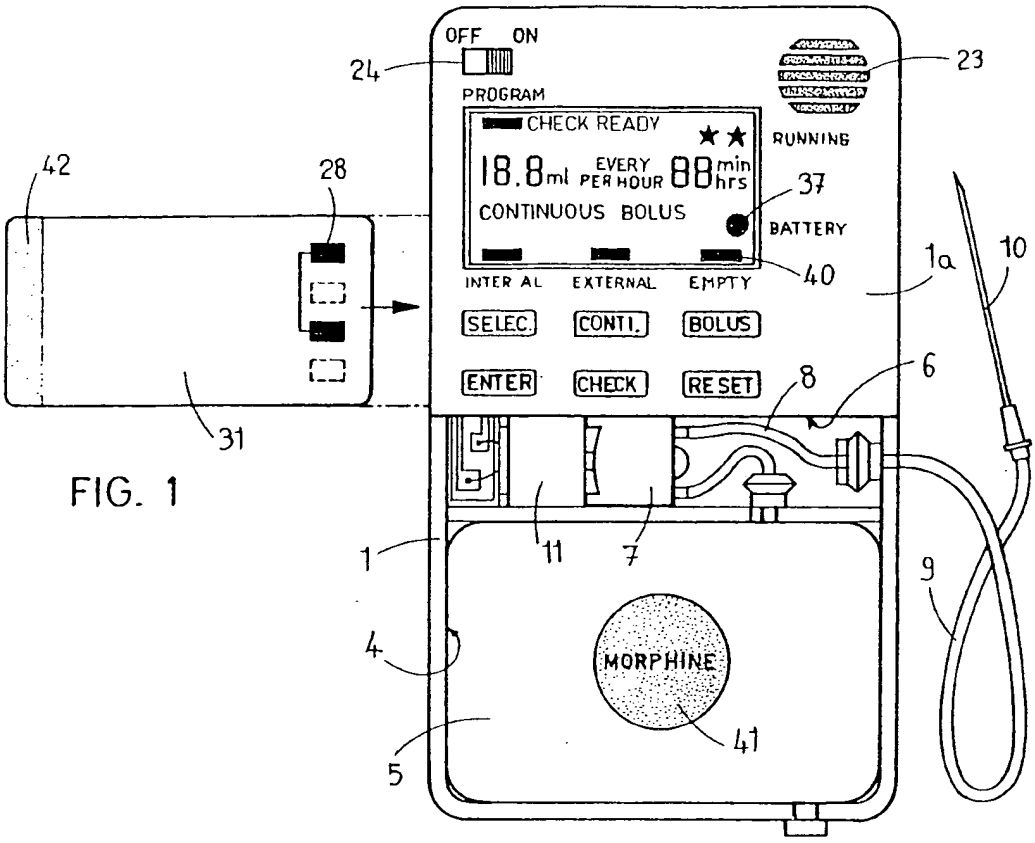


FIG. 1

FIG. 2

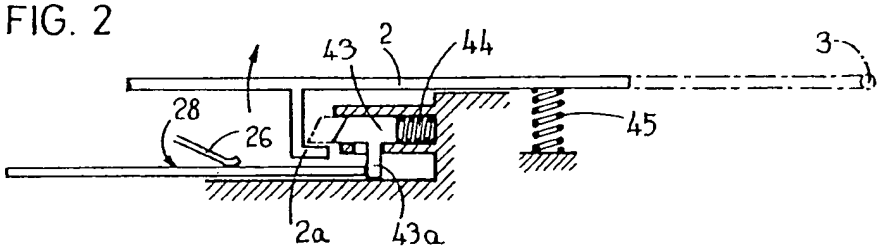


FIG. 4

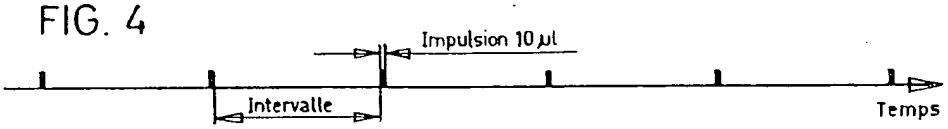
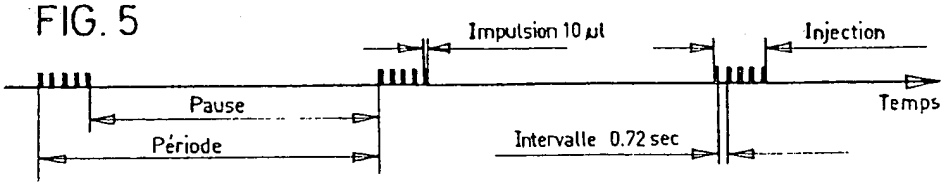


FIG. 5



665 955
2 feuilles N° 2

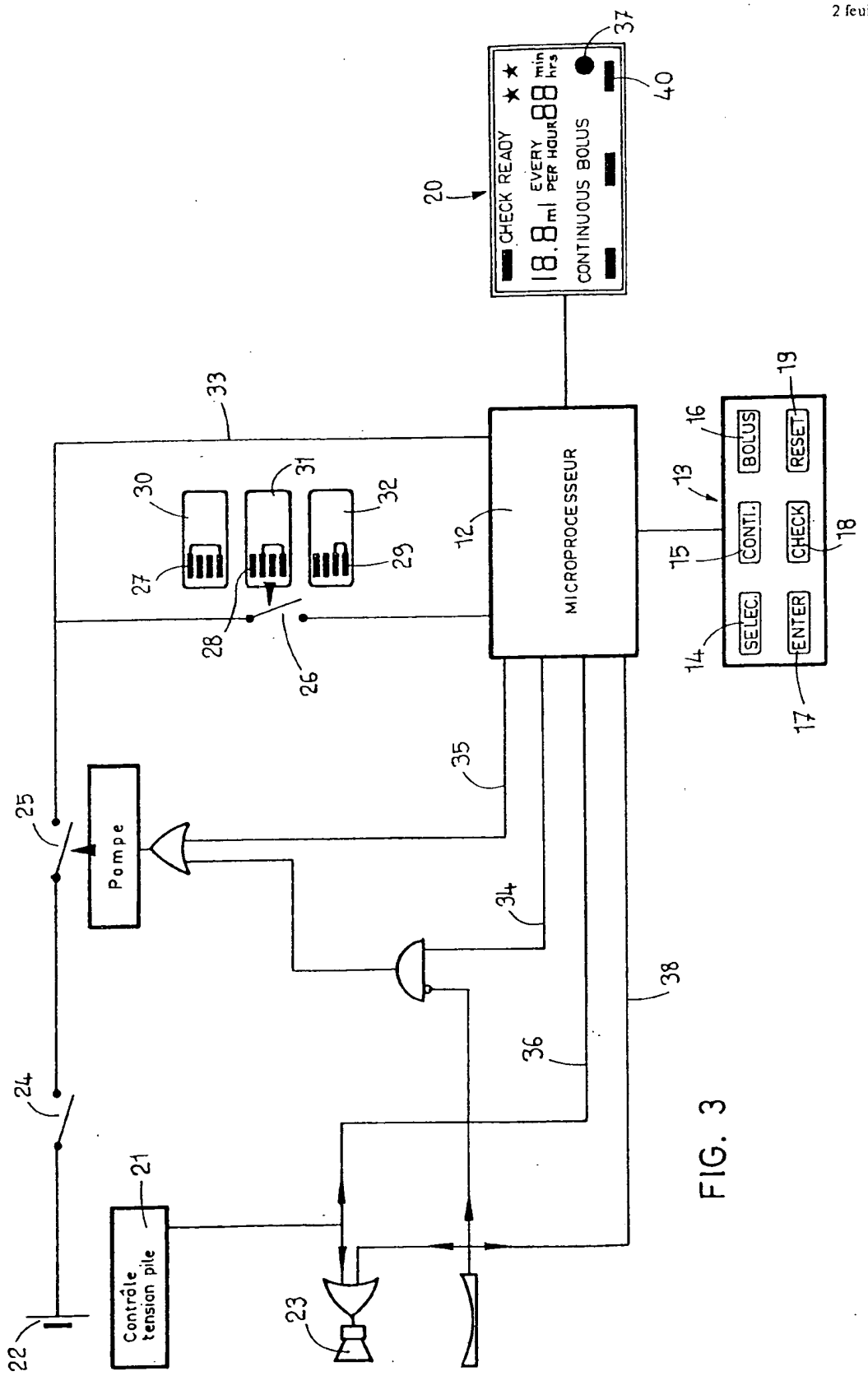


FIG. 3

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(71) Applicant: **C.R. BARD, INC.**
730 Central Avenue
Murray Hill New Jersey 07974(US)

(72) Inventor: **Samiotes, Nicholas**
185 Briar Lane
Westwood, Massachusetts(US)
Inventor: **Johanson, Donald**
27 Campbell Road
Wayland, Massachusetts(US)
Inventor: **Tamura, Paul**
5048 21st Avenue NE
Seattle, Washington(US)

(74) Representative: **JENSEN & SON**
70 Paul Street
London EC2A 4NA(GB)

(54) Automated infusion pump with replaceable memory cartridges.

(57) An infusion pump system for dispensing a drug to a patient in accordance with a predetermined therapeutic modality, said system including a drug delivering member 24 controlled by a microprocessor 34 and replaceable memory modules 38 coupled to said microprocessor 34 for configuring specific pump user interface and other characteristics required for differing therapeutic modalities. Information specific to a particular patient is entered through input features 42, 46 on the pump.

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This invention pertains to a microprocessor controlled infusion pump for delivering drugs to a patient, and more particularly to an infusion pump with a memory cartridge which defines one of a variety of configurations for the pump, said cartridges being replaceable to allow the pump to be used in multiple, different environments.

Infusion pumps are used in the field of medicine to administer drugs to patients over an extended time period particularly durations longer than can be managed easily by direct injection. As availability of drugs, therapeutic techniques, and technological capability have improved, the demand for sophistication in drug delivery has increased. In many instances, this added sophistication results in more complicated device operation. Achieving this sophistication in drug delivery capability, and maintaining ease of use has been a major challenge for infusion pump manufacturers.

One reason that devices have become complicated is the breadth of drug dosing methods used. For example, such different modes of operation as Patient Controlled Analgesia (PCA) and physician interactive dosing for operating room infusions must somehow be accommodated. Other current therapy modes in use include continuous infusion, bolus plus continuous infusion, clinician interactive dosing; PCA with continuous infusion, time/dose, and multiple automatic time/dose.

Continuous infusion is the most traditional method of drug delivery. Figure 1 shows a graph of a constant drug flow vs. time. The infusion rate may be changed, if necessary, but whatever rate is selected will continue indefinitely. In this type of infusion, the user only selects the rate in ml/hr or drops/minute.

Time/dose therapy is shown in figure 2. This therapy is accomplished with a number of different devices for many different drugs. One device, a syringe infusion pump described in U.S. Patent 4,544,369, has no rate input at all. The selection of syringe size and dose volume define the duration of infusion and, thus, the flow rate. Other devices have flow rate and dose volume as inputs. Still others require dose volume and duration of infusion as inputs. Intermittent medications such as antibiotics and H_2 agonists are often administered using these devices.

Figure 3 shows a multiple dose scheme. This method is similar to time/dose, but also includes a repeat time as a user defined parameter. The pump automatically starts each dose at predetermined time intervals.

Figure 4 shows patient controlled analgesia (PCA) therapy. The clinician typically selects a dose size, and a minimum delay or lockout period. The patient may request a drug dose using a bedside request button connected to the pump. The pump administers a dose only if it has been requested during the minimum time period after the administration of a previous dose.

Often, a continuous infusion is superimposed over PCA therapy as shown in Figure 5. The clinician must select a continuous infusion rate along with the dose size and minimum delay period. PCA therapy may also include additional clinician selectable features. These include a loading dose at the start of or during therapy and secondary prescription limits (e.g. hourly limit).

Interactive dosing is commonly done in the operating room (OR) or the intensive care unit (ICU). Figure 6 shows a typical course of therapy. The clinician selects appropriate rates, boluses, and changes based on patient response or therapeutic goal. Aspects of interactive dosing are common to all infusion schemes because the actual dosing requirements change from patient to patient and from time to time. Nevertheless, certain circumstances require rapid interactive dosing not necessarily available or even desirable on all devices. An example of a device particularly well suited for this type of interactive dosing is made by C.R. Bard and is described in U.S. Patent number 4,943,279.

Of particular importance to the foregoing discussion is the wide variety of user selectable primary dosing inputs. The range of possible user inputs includes, but is not limited to, infusion rate, infusion duration, dose volume, lockout period, repeat period, bolus size, and bolus rate. Secondary inputs may include patient weight, patient sex, syringe size, container volume, security codes, drug units (e.g. milligrams), drug concentration, or even pharmacokinetic parameters.

In addition, not only are the clinician inputs numerous and variable, but the infusion pump's outputs are also extensive. History and status information unique to each therapy must be presented to the user in a clear manner.

The totality of inputs and outputs is termed the user interface. This user interface often has one most desirable features for a particular therapeutic modality.

Because of the large number of therapeutic modalities and the extensive number of possible required inputs and outputs, the challenge to manufacturers has been great. Users desire most a user interface with only a particular set of inputs and outputs pertinent to a particular therapy. On the other hand, great versatility is desired by both the manufacturers and the users. Users desire versatility so their pumps can perform many therapies. Manufacturers have the same desire because the economies of scale can be more easily realized.

The infusion industry has collectively responded to these needs in a number of ways. First,

compromises in features are often accepted in the interest of having versatile, general or multi-purpose pumps. For example, users may sometimes select doses based on body weight and drug units, but often times this may not be current practice for some drugs. Therefore when necessary, users perform conversion calculations so that reates may be selected in ml/hr. These calculations are time consuming and are potential error sources. Another example is that continuous infusion modes may be used for time/dose infusions. The user must either time the infusion or rely on "end of container" alarms to appropriately terminate delivery.

An alternate to general purpose pumps has been devices designed specifically for only one drug or therapy. This have proven desirable for some widespread therapies. Users value the simple operation of these devices since they include only those features needed for a particular therapy. The disadvantages of these devices is their lack of versatility. They usually cannot perform widely differing therapies, not can they accommodate therapy advance over time.

In view of the above-mentioned disadvantages of the prior art, it is an objective of the present invention to provide an infusion pump system with variable user interface characteristics.

A further objective is to provide an infusion pump system which may be operated as a pump having particular user interface characteristics by using a replaceable memory module.

Yet another objective is to provide a pump system with user interface means thereon for adjusting the operation of the system in accordance with the needs and requirements of a particular patient.

Other objectives and advantages of the invention shall become apparent from the following description.

According to the present invention there is provided an infusion pump system for dispensing a drug to a patient comprising:

a. reservoir means for holding a drug;

b. delivery means for delivering said drug to said patient;

c. delivery control means for activating said delivery means, said delivery control system including:

(i) microprocessor means for operating said delivery means;

(ii) a set of memory modules, each module containing information defining a specific user interface; and

(iii) coupling means for accepting one of said memory modules, and coupling said one memory module to said microprocessor, wherein said microprocessor reads said information and operates said delivery means in conformance with said specific user interface.

The memory module, which may comprise a cartridge, is used to configure the infusion pump system, and particularly the control means, to a particular user interface and to particular functional characteristics. The control means further includes keypads, rotary knobs, or other means of inputting specific dosing or patient information to the microprocessor. The control means further still includes display, alarm, or other means for communicating with the user. The control means also provides operating and monitoring means indicative of the internal functions of the infusion pump.

Figure 1-6 show time charts for various kinds of infusion that can be performed with an infusion pump constructed in accordance with this invention;

Figure 7 shows an elevational view of an infusion pump constructed in accordance with this invention;

Figure 8 shows a schematic diagram for the control of the infusion pump of Figure 7; and

Figure 9 shows an elevational view of an alternate embodiment of the infusion pump.

As shown in the Figures, and more particularly in Figure 7 an infusion pump 10 may include a housing 12 with a front 14 used to hold various control and display means used to set up and operate the pump as described more fully below. The housing 12 may include mounting means (not shown) for securing the pump to an IV pole or another stationary frame.

On one side of the housing the pump is provided with a bracket 20, for engaging and holding the barrel 24 of a syringe. The bracket 20, may include sensors for sensing the diameter of syringe barrel 24. The syringe also includes a plunger 26 reciprocated in the barrel 24. The plunger 26 is terminated by a flange 28 which is captured by a plunger activating assembly 30. Assembly 30 is coupled to and driven by a motor (shown in Figure 8) up or down to permit the plunger 26 to be inserted into or out of syringe barrel 24. Thus, in Figure 7 the downward movement of assembly 30 causes the plunger 26 to eject the contents of the syringe barrel 24 either directly into the blood stream of a patient through a catheter device or into an IV through line 25. Therefore, the delivery of the drug from syringe barrel 24 to the patient is controllable through the vertical downwardly movement of the assembly 30 as well as the size of the syringe.

Inside the housing 12, there is the motor mentioned above for driving assembly 30, and a control system 32 shown in more detail in Figure 8. The control system 32 includes a microprocessor 34, which is coupled to a RAM 36 as well as several

input and output devices. RAM 36 is the random access memory for the microprocessor and holds appropriate memory for the pump. Importantly, the system 34 also includes replaceable ROM cartridge 38. As shown in Figure 7, the housing 12 has a slot 40 accessible from the outside for holding ROM cartridge 38 so that the ROM cartridge 38 is readily removable and replaceable with another cartridge. Instructions and patient specific data are provided to microprocessor 34 from a standard keypad 42 and some additional control push-buttons 46. All these input devices are mounted on the face 14 of housing 12 as shown in Figure 7. In addition the system is also provided with a screen such as an LCD-type screen 48, and alarms, including attention light 51 used to indicate an abnormal pump operation. The size of barrel 24 is determined from condition sensors 60 which may be mounted in brackets 20, 22. Microprocessor 34 generates control signals to a mechanical which are used to drive motor 52 for activating the plunger. The position of motor 52 is sensed by a motor sensor 54 and sent back to the microprocessor for verification. Optionally, a printer interface may also be provided for printing data from the microprocessor 34 to an external printer 56.

The general operation of the infusion pump shall now be described. Initially, a ROM cartridge 38 corresponding to a specific delivery profile, such as one of the profiles shown in Figures 1-6, is loaded into slot 40. In other words a ROM 38 is provided for each specific user interface, thereby defining the characteristics of a dedicated pump. The microprocessor 34 reads this information from the cartridge 38. Next, the microprocessor provides operational instructions on LCD display 48 and, if necessary, requests patient-specific information. In other words, display 48 is used to request dosing inputs such as flow rate, dose size, patient weight, drug concentration, etc., as required. The display 48 may also be used to identify the cartridge inserted in slot 40, and other initial information such as the size of the barrel as determined by the sensors 60, thereby providing a further means to insure that the pump is operated properly and that the patient will receive the correct drug dose. The operator of the pump enters the requested information through the key pad 42. The remaining control push buttons 46 may be dedicated to other functions such as a review function (46A) during which the information provided to the microprocessor is reviewed prior to the operation of the pump, or to start or stop the pump, by activating push button 46B.

Once the requested information is entered, the microprocessor 34 adjusts the operational parameters for the pump to meet the requirements of the specific patient, and on command, for example, from push button 46B starts the infusion. The microprocessor monitors the operation of the pump on a continuous basis, and in case of a malfunction, it activates alarm light 51 and/or any other alarms 50.

To summarize, the pump 10 may be used for infusion using the characteristic/parameters corresponding to a specific user interface defined by cartridge 38 to act as a particular type of, or dedicated pump. The operation parameters and user interface of the pump, as well as the procedure for administering a particular drug are all stored in a cartridge 38. Patient specific information and other information, are provided to the microprocessor during an initialization phase via the input means provided on face 14. As desired, cartridge 38 may be changed to a different user interface to implement another pump having different operational parameters, for administering a different drug or therapy. In this manner a single type of infusion pump is used to emulate a large number of pumps. If technical advances and/or new regulations require a new infusion profile, the pump is easily reconfigured by providing an appropriate cartridge 38. Furthermore, the cartridges are easily installed in the field by personnel with no programming knowledge or capability.

Figure 9 shows an alternate embodiment 110 of the infusion pump. Pump 110 includes housing 112 with bracket 120, disposed on one side with a corresponding plunger activating assembly 130. Housing 112 also has a face 114 with data entry and control push buttons 142, a rotary switch 144 and an LCD screen 148. Disposed below the key 142, there is a slot 140 for accepting a ROM cartridge 138. The operation of this embodiment is identical to the operation of the pump illustrated in types 7 and 8.

The infusion pump described herein has a number of benefits and advantages. A single pump may be used to serve multiple needs of a user in a single facility. The operation of the device is simplified since the instructions for setting up the pump for a particular operation are presented to the user one step at a time on the screen.

Existing applications, for example, to conform to changes in drug concentrations, acceptable usage, etc. may be easily updated without changing the pump. The pump can be easily configured for future applications.

Moreover, because each cartridge dedicates a pump to a specific pump configuration for each application, the pump is only as complicated as needed to perform thos applications.

Software upgrades are easily implemented, thereby insuring greatly the pump's useful life.

The pump can be easily configured for special applications, thereby reducing development costs

considerably.

The pump can be easily configured to accommodate new drugs and techniques.

Finally, a user is free to buy only the ROM cartridges for his specific application, with the option of buying more as required, or as they because available. Although the memory modules are described as ROM cartridges it will be appreciated that other forms of date storage such as dics or CD Roms may be used.

Obviously numerous modifications can be made to this invention without departing form its scope as defined in the appended claims.

Claims

1. An infusion pump system for dispensing a drug to a patient comprising:
   a. reservoir means for holding a drug:
   b. delivery means for delivering said drug to said patient;
   c. delivery control means for activating said delivery means, said delivery control system including:
      (i) microprocessor means for operating said delivery means;
      (ii) a set of memory modules, each module containing information defining a specific user interface; and
      (iii) coupling means for accepting one of said memory modules, and coupling said one memory module to said microprocessor, wherein said microprocessor reads said information and operates said delivery means in conformance with said specific user interface.

2. The system of claim 1 further comprising input means disposed on said housing for providing patient specific data to said microprocessor means.

3. The system of claim 1 or 2, further comprising display means disposed on said housing for displaying output data.

4. The system of claim 1, 2 or 3, wherein said information defines parameters for configuring said pump to mimic a dedicated pump having specific operational characteristics.

5. An infusion pump system for dispensing a drug to a patient, said system comprising:
   a. a set of memory modules, each memory module containing information defining a specific user interface;
   b. a housing with memory access means for replaceably accepting one of said memory modules;
   c. reservoir means mounted on said housing for holding a drug;
   d. drug delivery means for delivering said drug from said reservoir to said patient; and
   e. delivery control means mounted in said housing for operating said drug delivery means, said delivery control means including microprocessor means coupled to said one memory module, said microprocessor means receiving said information from said one memory module to operate said delivery means in conformance with the specific user interface defined by the information in said one memory module.

6. The system of claim 5 further comprising input means mounted on said housing for inputing patient specific data to said microprocessor means.

7. The system of claim 5 or 6, further comprising display means mounted on said housing for displaying output data from said microprocessor.

8. The system of claim 5, 6, or 7, wherein said display means includes a display panel for displaying operational instructions.

9. The system of claim 7 or 8 wherein said display means includes an alarm indicator for indicating an abnormal operating condition.

10. The system of any one of claims 5 to 9, further comprising manual control means mounted on said housing.

11. The system of claim 10 wherein said manual control means includes manual keys disposed on said housing.

12. A method of administering a drug to a patient comprising the steps of:
   a. providing an infusion pump system having a reservoir with a drug, a delivery means for delivering said drug to a patient, and a delivery control means including a microprocessor for operating said delivery means, and a set of memory modules, each module containing information defining a specific user interface;
   b. selecting a specific memory module; and
   c. coupling said specific memory module to said microprocessor, wherein said microprocessor operates said delivery means in conformance with said specific user interface.

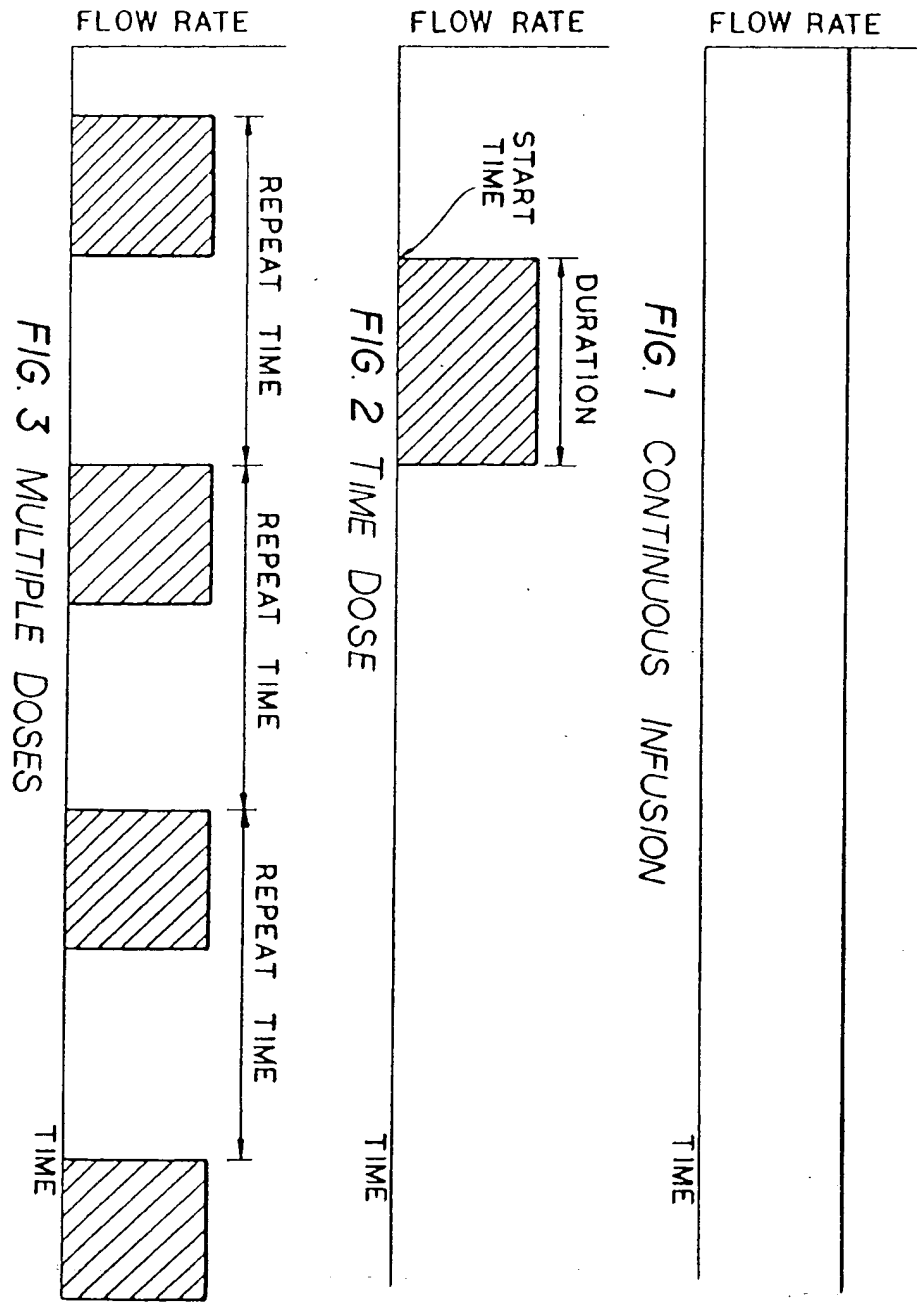

FIG. 1 CONTINUOUS INFUSION

FIG. 2 TIME DOSE

FIG. 3 MULTIPLE DOSES

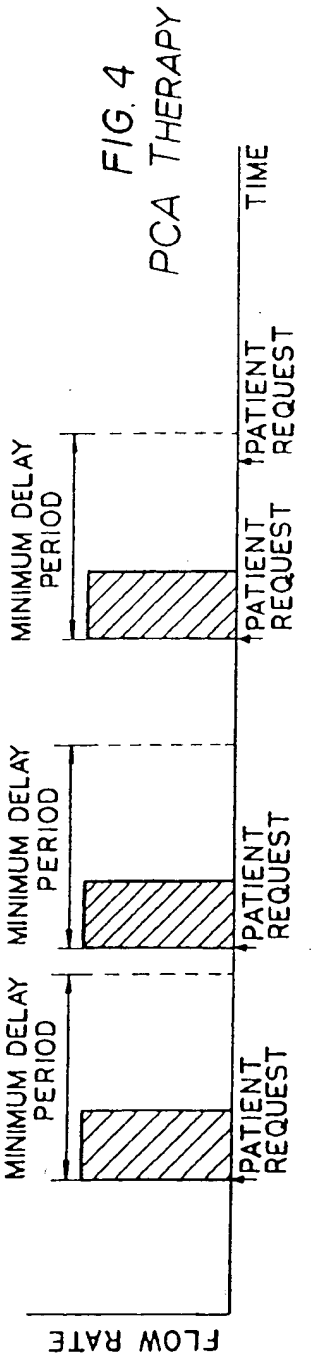

FIG. 4
PCA THERAPY

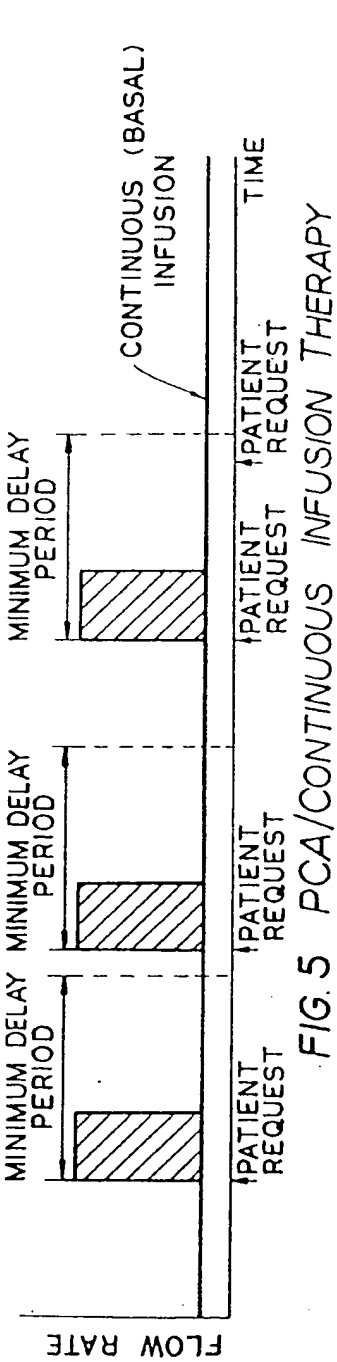

FIG. 5 PCA/CONTINUOUS INFUSION THERAPY

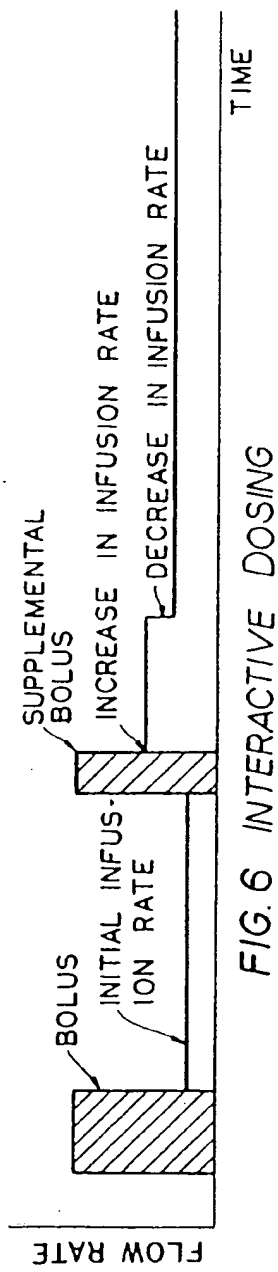

FIG. 6 INTERACTIVE DOSING

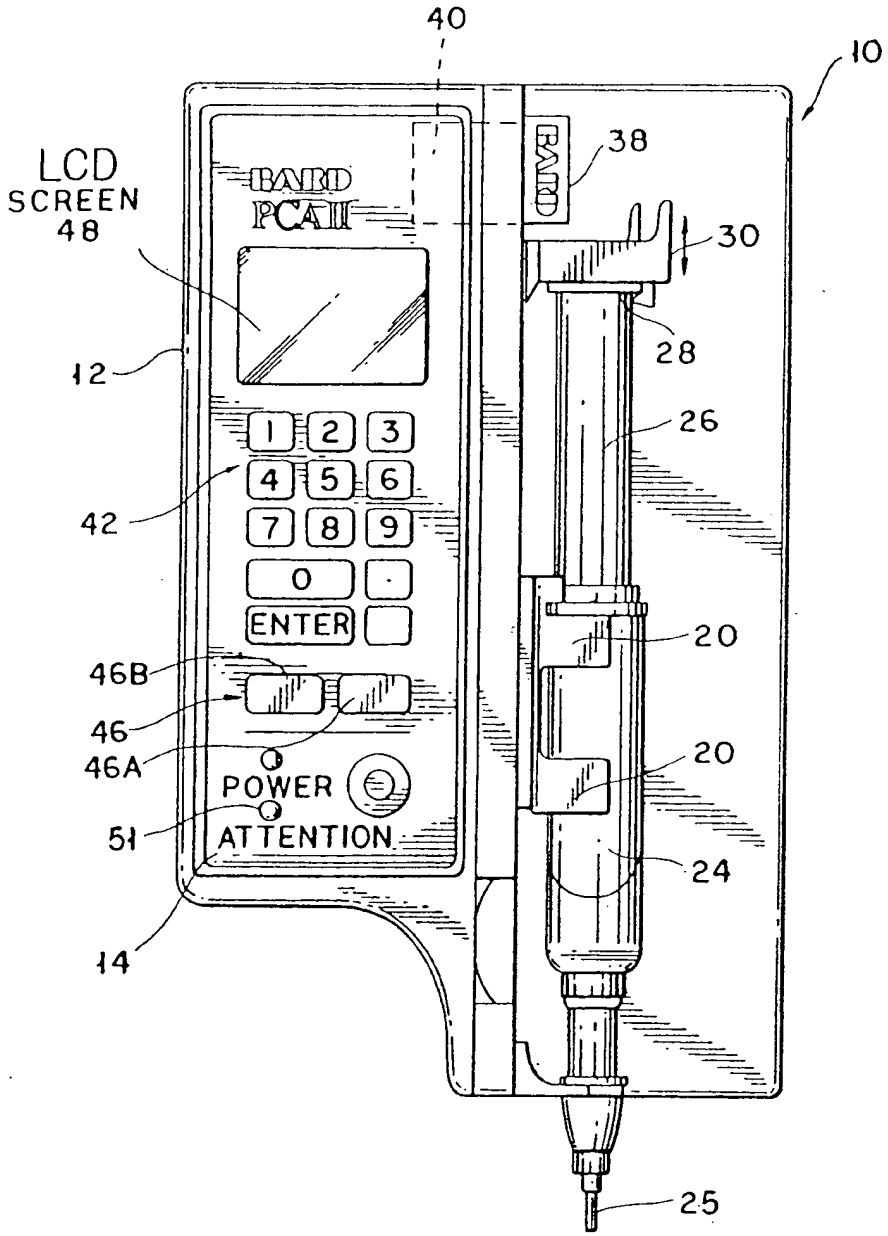
40
10
LCD
SCREEN
48
BAIRD
PCA II
BAIRD
38
30
28
12
26
42
1 2 3
4 5 6
7 8 9
0 .
ENTER
20
46B
46
46A
20
POWER
51
ATTENTION
24
14
25

FIG. 7

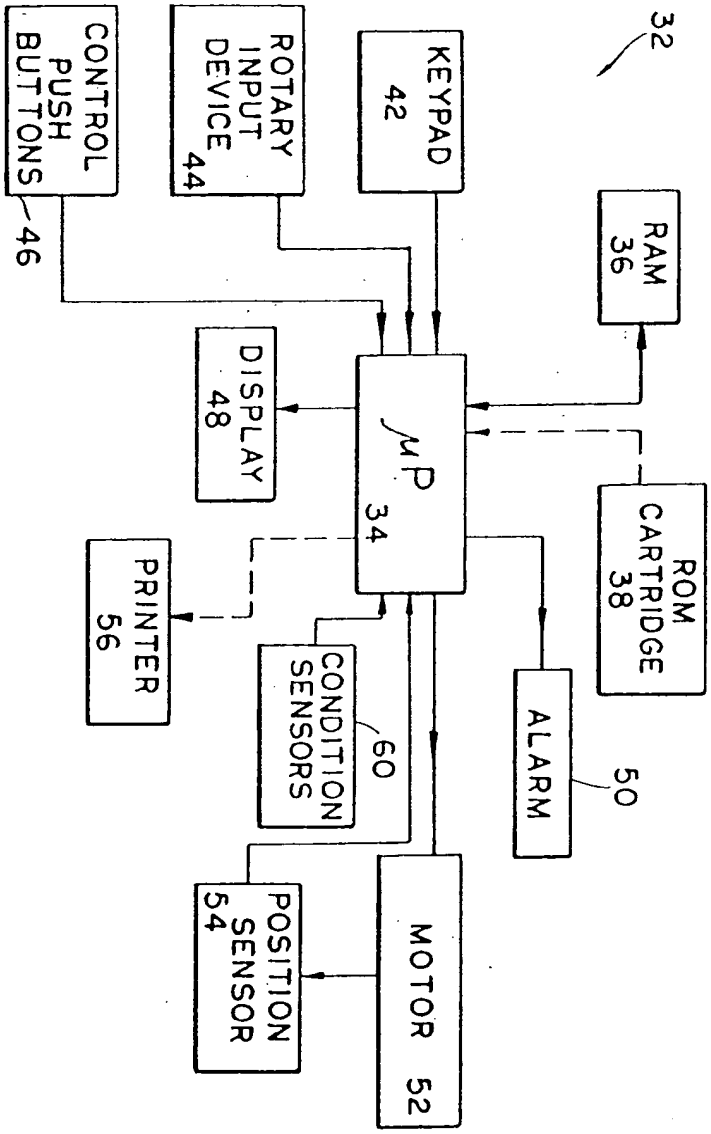
32
CONTROL PUSH BUTTONS
46
ROTARY INPUT DEVICE 44
KEYPAD 42
RAM 36
DISPLAY 48
μP 34
ROM CARTRIDGE 38
PRINTER 56
CONDITION SENSORS 60
ALARM 50
POSITION SENSOR 54
MOTOR 52

FIG. 8

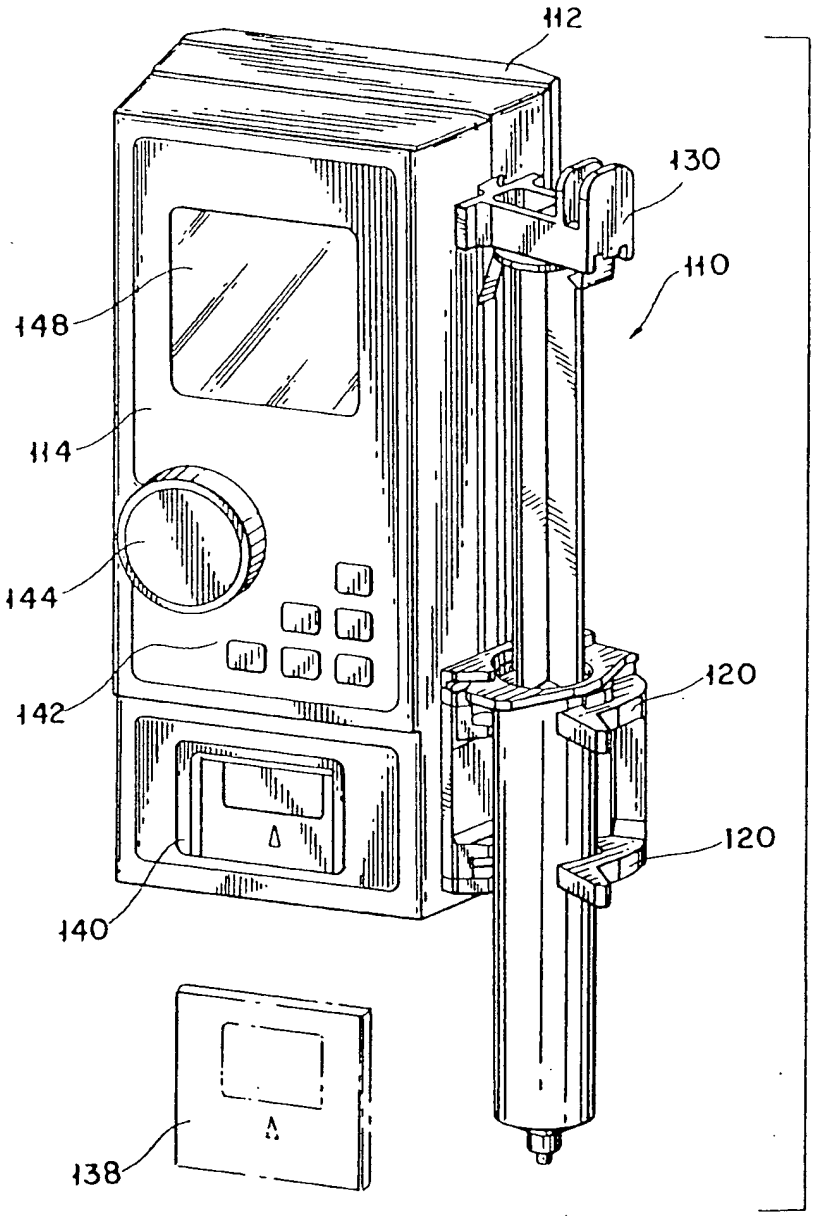

FIG. 9

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 31 0459

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	CH-A-665 955 (UNIVERSO S.A.) * column 2, line 9 - line 14 * * column 2, line 31 * * column 2, line 37 * * column 2, line 48 - line 56 * * abstract; claim 1; figures 1-5 * ---	1-12	A61M5/172
X	EP-A-0 188 288 (INTELLIGENT MEDICINE, INC.) * page 16, line 6 - line 12 * * page 17, line 20 - line 24 * * page 18, line 12 - line 19 * * page 21, line 23 * * page 24, line 4 - line 5 * * page 24, line 10; figures 2,4 * ---	1-8, 10-12	
A	EP-A-0 002 775 (SIEMENS A.G.) * page 7, line 32 - line 34; figure 1 * * page 8, line 27 - line 29 * * page 10, line 5 - line 7; figures 2,3 * * abstract * -----	1,4,5,8, 9,12	TECHNICAL FIELDS SEARCHED (Int. Cl.5) A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	22 MAY 1992	SEDY R.

CATEGORY OF CITED DOCUMENTS

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E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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(71) Applicant *(for all designated States except US)*: GRASEBY MEDICAL LIMITED [GB/GB]; Colonial Way, Watford, Hertfordshire WD2 4LG (GB).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)* : LINDSEY, Michael, John [GB/GB]; 366 High Street, Berkhampsted, Hertfordshire HP4 1HU (GB).

(74) Agents: MAGGS, Michael, Norman et al.; Kilburn & Strode, 30 John Street, London WC1N 2DD (GB).

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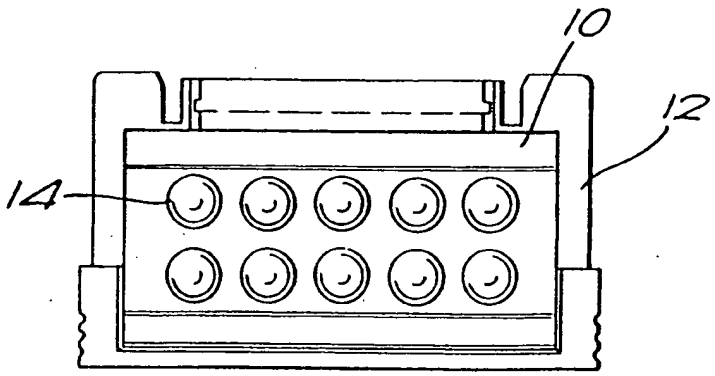
With international search report.

(54) Title: PROGRAM CARD



(57) Abstract

A host apparatus (for example medical infusion pump equipment) is operated by means of controls on a replaceable program card/electronic card. A selection of different cards is provided, programmed differently, which allows the user of the apparatus to select between different operating regimes. Different cards may also provide for messages in different languages on an alphanumeric display.

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PROGRAM CARD

The present invention relates to so-called "electronic cards" or electronic modules, and particularly although not exclusively to such cards or modules which come in a variety of types, one of which is selected by the user and plugged in or otherwise attached to a host apparatus. By choosing an appropriate card, the user can arrange for the host apparatus to operate according to one of a number of possible modes. The program card may also include additional memory for the host apparatus.

The use of such cards is well known in association with personal computers, and with complex electronically controlled apparatus such as cameras, both of which incorporate the necessary electronic processors and memory to provide the apparatus with a basic range of user-controllable functions, which may be further extended by use of electronic cards.

The present invention provides an electronic card which itself incorporates user-adjustable controls, thereby enabling a user to control, modify or adjust the functioning of the program card and/or to control modify or adjust the functioning of the host apparatus.

One embodiment of the invention, an electronic card in accordance with the invention provides the whole control function for the associated apparatus, thereby enabling a basic apparatus to be provided with a range of different functions, or sets of functions, by appropriate change of electronic card.

The electronic card of such an embodiment may incorporate and/or provide the control panel of the associated apparatus.

In one application of the invention, medical infusion pump equipment comprising an electric pump, pressure sensor, electrically-operated fluid control valves and an electronic display, is able to provide a range of different infusion regimes by choice of an electronic card, each one of which incorporates the appropriate controlling software and user controls for the respective regime.

The individual electronic cards may be marked to indicate the regime provided, may be provided in versions having control markings in different languages and may be programmed to give display indications in a corresponding range of languages.

It will be appreciated that an electronic card in accordance with the present invention provides a ready means of selecting the operating mode or regime of a basic piece of equipment, providing the user controls for that equipment, and of tailoring that equipment for sale into and use in markets with different languages.

The invention will be described by way of example with reference to the embodiment illustrated in the accompanying drawings of which:

Figure 1 shows an assembled controllable program card in accordance with the invention;

Figure 2 shows interior detail of the card of Figure 1;

Figure 3 shows the circuit diagram of circuitry incorporated in the card of Figure 1;

Figure 4 shows the front elevation of a medical infusion pump assembly adapted to receive the card of Figure 1;

Figure 5 shows the location of the card in the upper portion of the assembly of Figure 4; and

Figure 6 shows the upper part of the assembly of

Figure 4 with the card in place.

Referring to the drawings, an electronic card in accordance with the preferred embodiment of the invention is shown at 10, mounted with a carrier 12. The card bears switch buttons 14 forming part of a membrane switch assembly within the body of the card. The switches operate to control various functions of apparatus with which the card is associated, via the electronic circuitry incorporated in the card.

Figure 2 illustrates the printed circuit board 20 incorporated within the card 10, carrying membrane switch pads 22, associated with the switch buttons 14, integrated circuits 24 and 26, and an electrical connector socket 28.

The circuit diagram of the electronic assembly carried by the board 20 is illustrated in Figure 3, the same parts carrying the same reference numerals.

Referring to Figure 4, a medical infusion pump assembly comprises a housing 40 incorporating pump, electromechanical valves, pressure sensor(s) (not shown) and a flexible bag infusate reservoir 42. In operation the assembly is arranged to pump infusate from the reservoir 42 through flexible piping via controllable valves to the infusion cannula 44 to a patient, all under the control of software carried within an electronic card, such as 10, which is shown in Figure 5 being put into place in the upper part of the housing 40.

To do that, the head 44 is drawn upwardly (to the right in Figure 5), the program card 10 inserted in the recess 46, and the head 44 replaced into position, a mating connector (not shown) within the head 44 engaging with the socket 28 to effect electrical connection between the electronic card 10 and the infusion pump assembly 40.

In Figure 6, the infusion pump assembly 40 is shown with the card 10 in place, providing a front panel and control means for the pump assembly, to cause the components of the pump assembly 40 to function in a manner determined by the programming of the electronic card 10.

In a typical electronic card used in such an application the apparatus-controlling software is stored in reprogrammable flash memory, and operating date storage and history storage in an EEPROM device.

By providing a series of differently programmed cards 10, the same basic infusion pump assembly 40 can be made to function in different ways dependent upon the software program incorporated in the card plugged into the pump assembly.

The electronic card 10 may carry legends appropriate to the functions which it will permit the pump assembly to perform, and to the user controls, and may carry legends in the language of the user nationality.

The electronic card can, in addition to the programming associated with the pump functions, be programmed to deliver display messages in the language of the user.

It will be appreciated that various changes may be made without exceeding the scope of the invention. For example the electronic program card may be incorporated in other than medical instruments and may be incorporated in instruments already possessing control means, in which it could serve to provide a subsidiary control function.

CLAIMS:

1. An electronic card adapted to plug into or otherwise be removably attached to a host apparatus, the card having user-operable controls thereon by means of which, when the card is attached as aforesaid to a host apparatus, a user can control the operation of the host apparatus.

2. An electronic card as claimed in Claim 1 which is adapted to provide a replaceable user-operable control panel for the said host apparatus.

3. A host apparatus including a removable electronic card, the card having user-operable controls thereon by means of which the user can control the operation of the host apparatus.

4. A host apparatus as claimed in Claim 3 having no user-operable controls other than those on the card.

5. A host apparatus as claimed in Claim 3 or Claim 4 having an alphanumeric display, the card including display control means for controlling operation of the display.

6. A host apparatus as claimed in any one of Claims 3 to 5 in combination with a plurality of removable electronic cards, each of which is arranged to operate the host apparatus differently.

7. A host apparatus as claimed in Claim 6 when dependent upon Claim 5 in which the display control means

for each respective card is arranged to provide a display in a different language.

8. A host apparatus as claimed in any one of Claims 3 to 7 comprising medical infusion pump equipment.

9. A host apparatus as claimed in Claim 8 when dependent upon Claim 7 or upon Claim 6 in which each respective card provides a different infusion regime.

FIG. 1

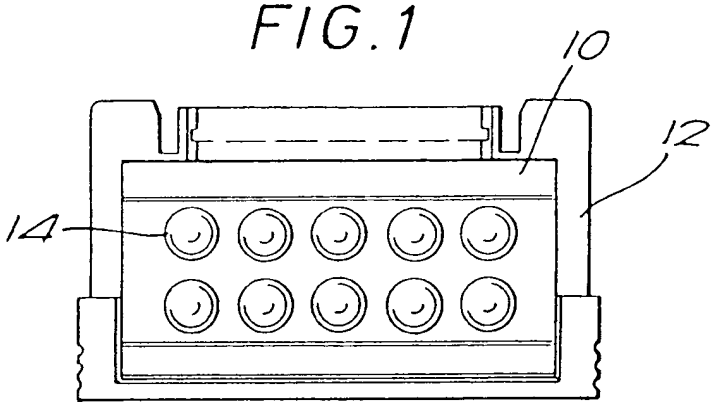


FIG. 2

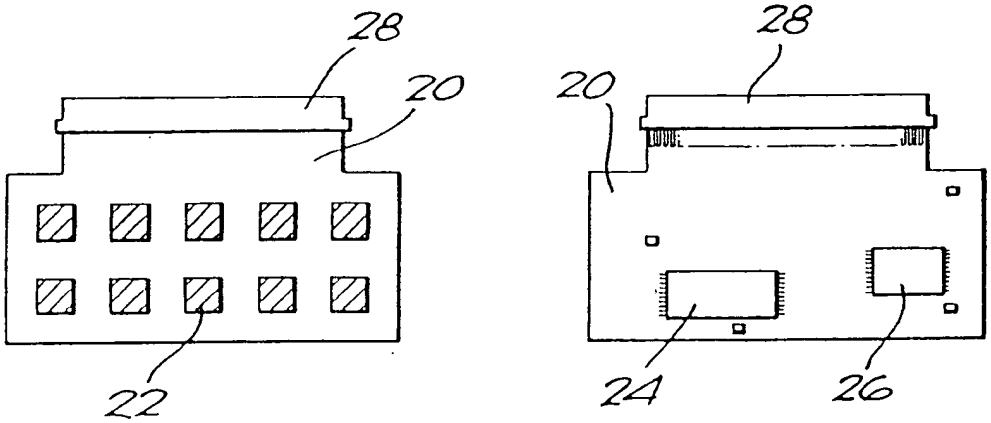
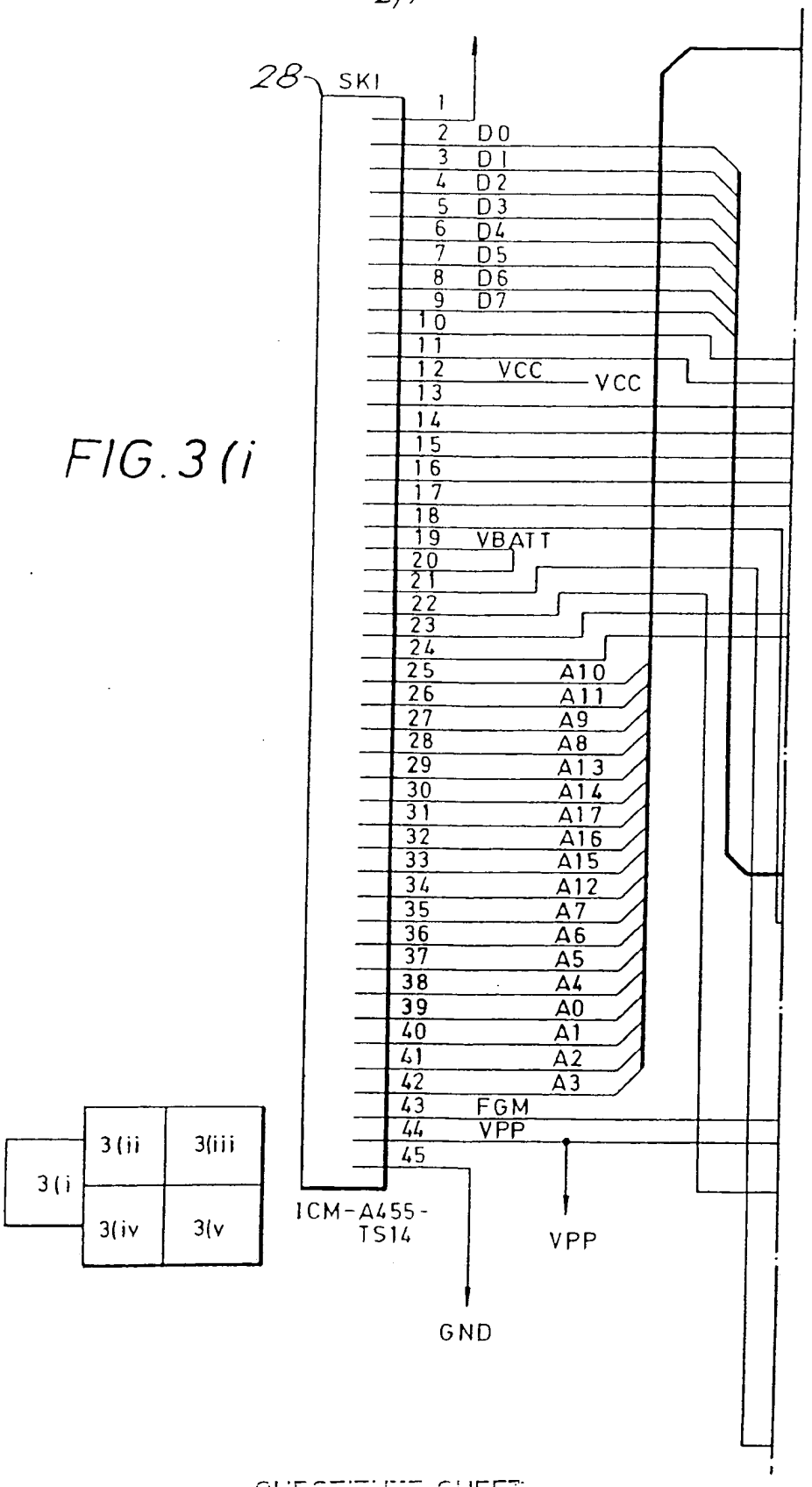


FIG. 3(i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1
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3 D1
4 D2
5 D3
6 D4
7 D5
8 D6
9 D7
10
11
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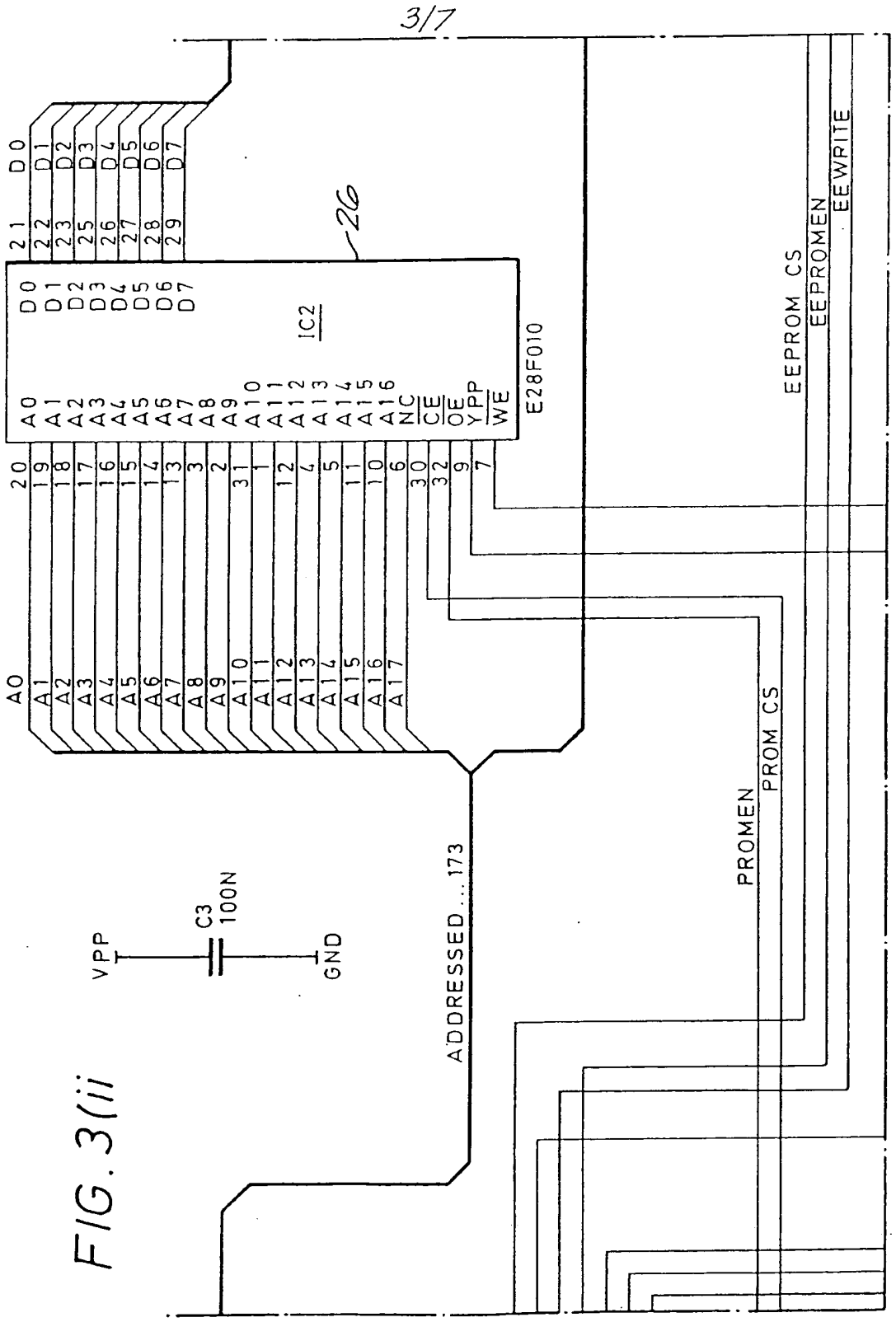
VCC
13
14
15
16
17
18
19 VBATT
20
21
22
23
24
25 A10
26 A11
27 A9
28 A8
29 A13
30 A14
31 A17
32 A16
33 A15
34 A12
35 A7
36 A6
37 A5
38 A4
39 A0
40 A1
41 A2
42 A3
43 FGM
44 VPP
45
3(i
3(ii
3(iii
3(iv
3(v
ICM-A455-TS14
VPP
GND


3/7
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E28F010
26
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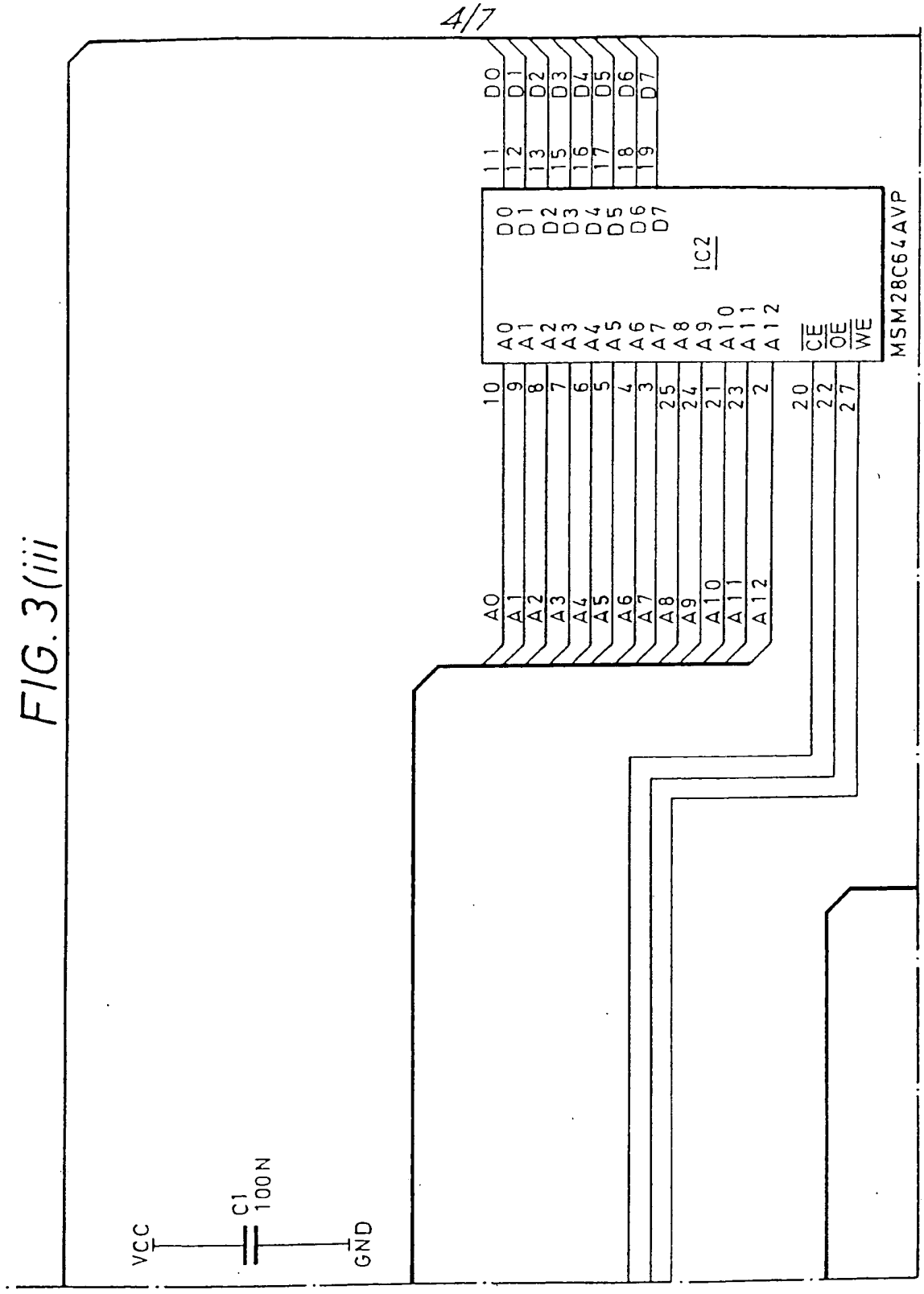
EEPROMEN
EEWRITE
PROMEN
PROM CS
ADDRESSED....173
VPP
C3
100N
GND

FIG. 3(ii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D2
D3
D4
D5
D6
D7
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12
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16
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18
19
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A0
A1
A2
A3
A4
A5
A6
A7
A8
A9
A10
A11
A12
CE
OE
WE
10
9
8
7
6
5
4
3
25
24
21
23
2
20
22
27
C1
100N
VCC
GND

FIG. 3(iii)

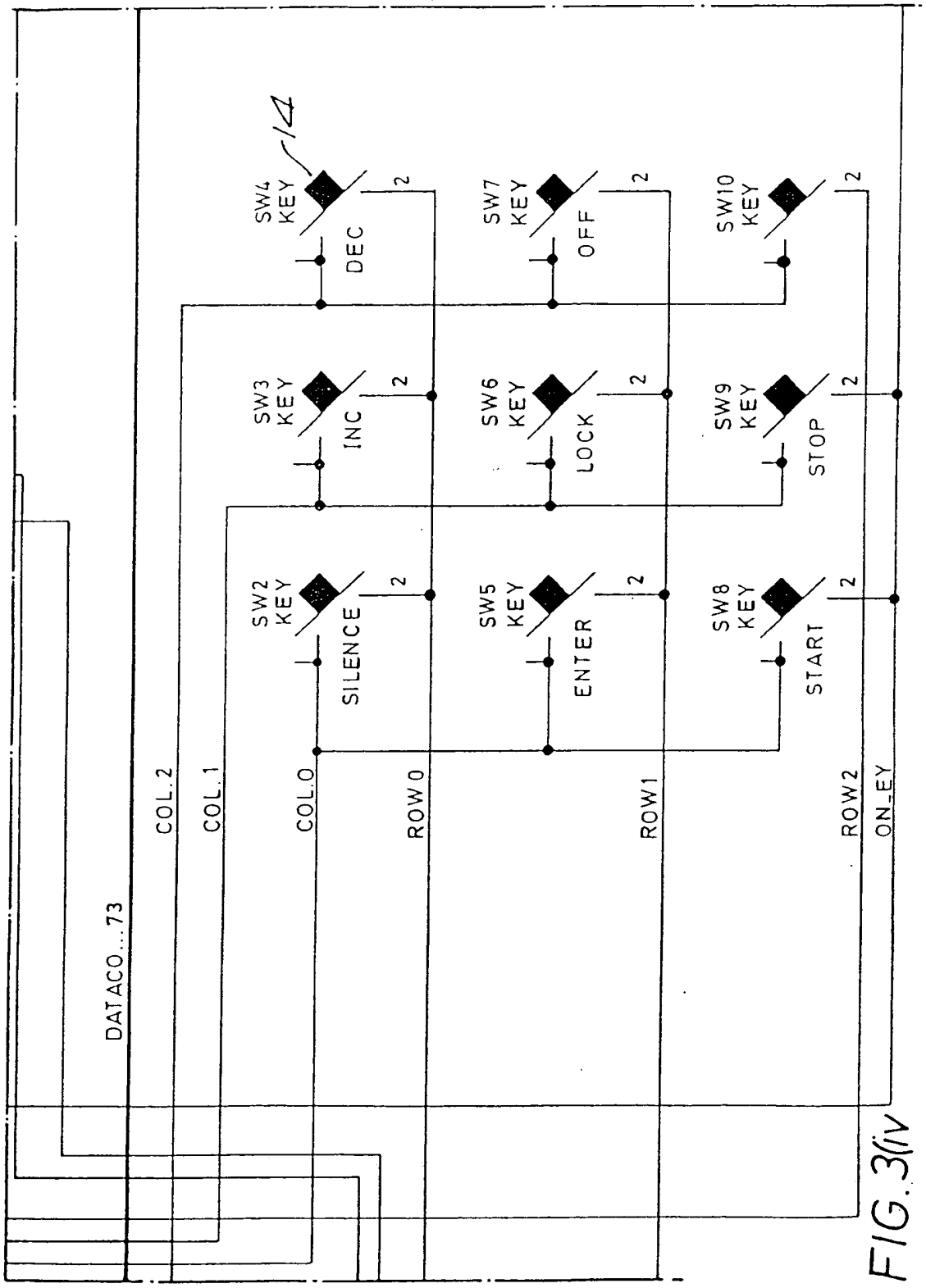

14
SW4 KEY
DEC
SW7 KEY
OFF
SW10 KEY
SW3 KEY
INC
SW6 KEY
LOCK
SW9 KEY
STOP
SW2 KEY
SILENCE
SW5 KEY
ENTER
SW8 KEY
START
2
DATACO....73
COL.2
COL.1
COL.0
ROW0
ROW1
ROW2
ON_EY

FIG. 3(iv)

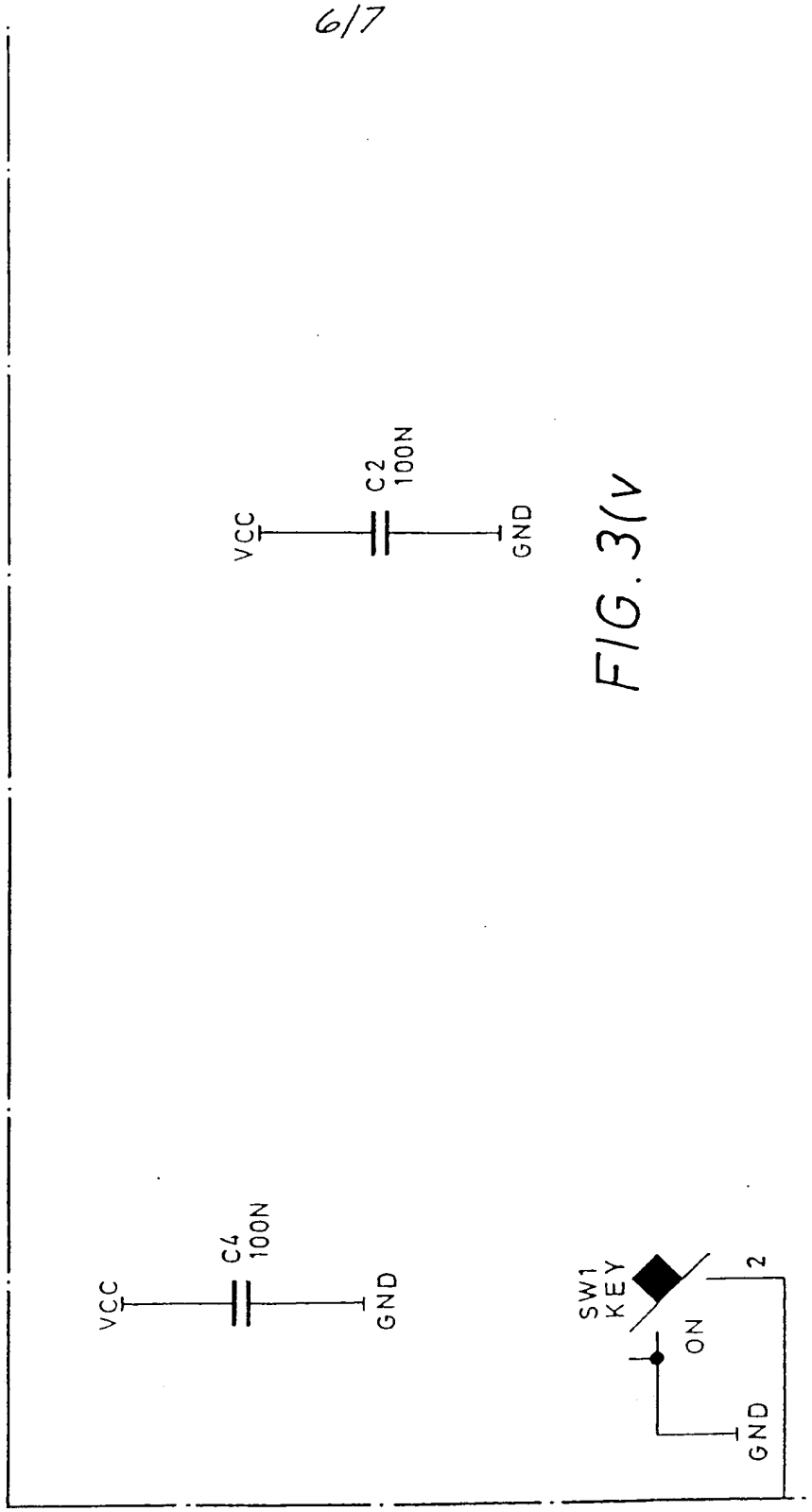


FIG. 3(v

FIG. 4

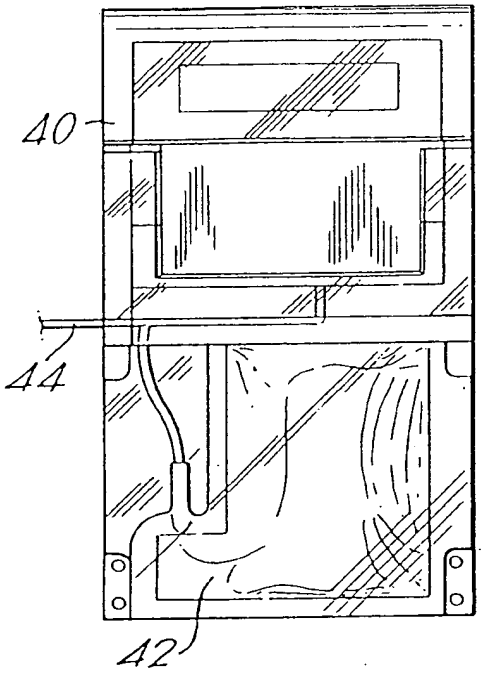


FIG. 5

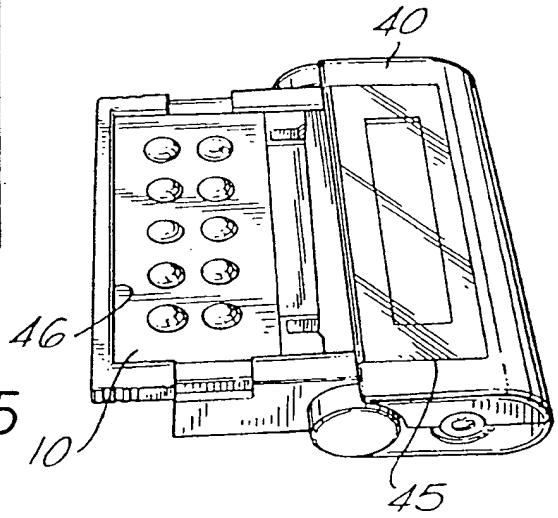
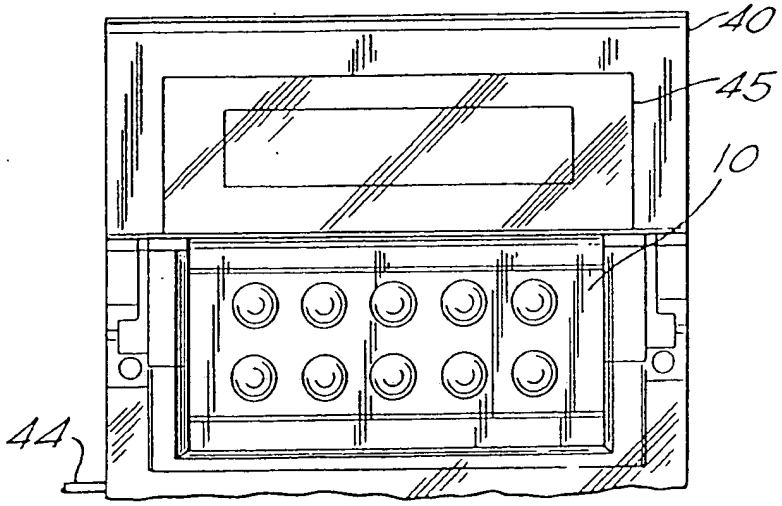


FIG. 6



INTERNATIONAL SEARCH REPORT

Inte ›nal Application No
PCT/GB 93/01965

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 G05B19/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 G05B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE,A,36 37 684 (SHARP K.K.) 7 May 1987 see abstract see column 1, line 63 - line 66 see column 2, line 21 - line 47 see column 5, line 15 - line 38 see figure 2	1-6
Y	---	7-9
X	FR,A,2 616 941 (PHOTOWATT INTERNATIONAL S.A.) 23 December 1988 see page 3, line 28 - line 32 see figure 2	1,3,4
A	---	2,5,6
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 November 1993	06. 01. 94

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Salvador, D

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INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/GB 93/01965

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR,A,2 583 538 (BRECHET MICHEL) 19 December 1986 see page 2, line 13 - line 27 see claims 1,6; figure 1	1,3,4
A	---	2,5,6,8
P,Y	DE,A,41 35 577 (FA. NORBERT NEU) 6 May 1993 see abstract	7
A	---	7
	EP,A,0 501 092 (COMELZ S.P.A.) 2 September 1992 see column 5, line 1 - line 12	
Y	---	8,9
	US,A,4 308 866 (JELLIFFE ET AL.) 5 January 1982 see abstract see column 4, line 27 - line 62 see figure 1	
A	---	1-4,6
	US,A,4 406 235 (EGUCHI) 27 September 1983 see the whole document	
A	---	8,9
	EP,A,0 316 280 (MEDICOMPEX S.A.) 17 May 1989 see abstract see claims; figure 1	

3

INTERNATIONAL SEARCH REPORT

information on patent family members

Inte onal Application No
PCT/GB 93/01965

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
DE-A-3637684	07-05-87	JP-B-	5014294	24-02-93
		JP-A-	62107360	18-05-87
FR-A-2616941	23-12-88	NONE		
FR-A-2583538	19-12-86	FR-A-	2608800	24-06-88
DE-A-4135577	06-05-93	NONE		
EP-A-0501092	02-09-92	NONE		
US-A-4308866	05-01-82	CA-A-	1146224	10-05-83
		CA-A-	1165403	10-04-84
		GB-A-	2039083	30-07-80
		JP-A-	55105771	13-08-80
US-A-4406235	27-09-83	NONE		
EP-A-0316280	17-05-89	CA-A-	1298621	07-04-92
		JP-A-	1155865	19-06-89
		US-A-	5033469	23-07-91

拒絶査定

特許出願の番号	特願２００１－５０１２８４
起案日	平成１６年　８月　４日
特許庁審査官	門前　浩一　　８７２３　３Ｅ００
発明の名称	コストを考えたアプリケーション注入装置
特許出願人	メドトロニック　ミニメド　インコーポレイテッド
代理人	吉田　研二（外　１名）

この出願については、平成１６年　３月１１日付け拒絶理由通知書に記載した理由によって、拒絶をすべきものである。

なお、意見書及び手続補正書の内容を検討したが、拒絶理由を覆すに足りる根拠が見いだせない。

備考

・請求項１－８に対して

先の引用文献７（実願平０２－１２６８９７号（実開平０４－０８３２５１号）のマイクロフィルム）の第３図及びその説明では、シリンジと分離可能な包装体にバーコードを設けており、ユーザー操作によりハンドスキャナで読み込んでいるが、このバーコード部分を筐体内部から読みとらせるために「ユーザー操作により筐体から着脱可能なタブ」に設けようとすることは当業者が容易になし得ることに過ぎないと認められる。なお、「ユーザー操作により筐体から着脱可能な」部材によりパラメータ値を変化させることは、他にも、スイス国特許出願公開第６６５９５５号明細書，国際公開第９４／０７１８６号パンフレット，欧州特許出願公開第４９７０４１号明細書に示されているようにこの出願前周知の事項であったと認められる。

上記はファイルに記録されている事項と相違ないことを認証する。

認証日　平成16年 8月 5日　経済産業事務官　高渕　清士

DECISION OF FINAL REJECTION

Patent Application Serial No. 2001-501284

Date of drafting: August 4, 2004
Mailed Date: August 10, 2004
Examiner: Kouichi MONZEN
Title of the Invention: COST-SENSITIVE APPLICATION INFUSION DEVICE
Applicant: Medtronic MiniMed, Inc.
Attorneys: Kenji YOSHIDA and one other

This patent application has been finally rejected for the grounds as stated in the Notice of Grounds for Rejection dated March 11, 2004.

The applicant' arguments and amendments have been reviewed, but they are not found to overcome the grounds for rejections in the previous Notice of Grounds for Rejection.

Remarks:

With regard to claims 1 to 8

In Reference 7 cited in the previous Notice for Grounds for Rejection (Japanese Utility Model Application No. Hei 02-126897 (Japanese Utility Model Laid-Open Publication No. Hei 04-083251)), Fig. 3 and the relevant description thereof discloses that a barcode is provided on a package which can be separated from a syringe and the barcode is read by a hand scanner through user manipulation. However, it is believed to be nothing but a matter which can be easily achieved by a person with ordinary skill in the art to provide this barcode section on "a removable tab which is removed from the housing through user manipulation" in order to cause the barcode to be read from the interior of the housing. Further, changing of a parameter value by a component "which can be removed from the housing through user manipulation" is determined to be a matter which was well known prior to the filing of the present application, as also disclosed in Swiss Patent Laid-Open Publication No. 665955 (specification), International Publication No. WO94/097186, and EP Laid-Open Publication No. 497041.